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**THE U.S. AIR FORCE
PHOTOREFRACTIVE
KERATECTOMY (PRK) STUDY:
Evaluation of Residual Refractive Error
and High- and Low-Contrast Visual
Acuity**

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1.0 SUMMARY

While corneal refractive surgery offers the potential to reduce dependence on optical appliances and widen the potential candidate pool, residual optical effects from such elective surgery can impact quality of vision and visual performance not identified using the traditional 20/20 standard derived from a high contrast Snellen-type letter chart. The major area of postoperative concern following photorefractive keratectomy (PRK) found in this study was the potential for residual refractive errors. Post-PRK refractive complications may include undercorrection, overcorrection, induced astigmatism, and anisometropia. The primary concern for distance visual acuity was undercorrection and/or regression over time similar to previous myopic trends reported in other U.S. Air Force studies of pilots between Undergraduate Pilot Training and later in their flying careers. Low to moderate residual refractive error after refractive surgery may be operationally significant in aviators, especially if not optimally corrected. The prevalence was relatively high in this study for PRK-treated eyes to have low to moderate residual refractive errors, defined as equal to or more than -0.50 D of myopia (spherical equivalent) on cycloplegic refraction. Yet, very few of these subjects wore corrective lenses to meet current standards. Larger amounts of preoperative myopia outside the criteria of this study would be expected to have less likelihood of achieving emmetropia post-PRK. When tested with best optical correction, however, performance on the various charts often improved to as good as, or better than, pre-PRK baseline values. The fundamental question is whether most individuals, particularly aviators, will wear relatively minor optical corrections in spectacles after refractive surgery, especially if they meet the current 20/20 requirement uncorrected and are therefore not required to wear corrective lenses. Failure to do so, however, may mean that certain visual performance parameters would be compromised and could potentially result in operational limitations of significance. For example, pilots who are only 20/20 uncorrected after PRK would need two times the distance to acquire and/or identify certain targets as compared to their performance when best corrected preoperatively to a possible 20/10 with spectacles or contact lenses. Potentially large differences may exist in target acquisition distances for detecting a bogey (10 miles versus 5 miles) and in critical reaction times. Additionally, uncorrected refractive errors, however trivial, may result in visual performance compromises, such as reduced contrast sensitivity and degraded performance under impoverished environmental conditions.

2.0 INTRODUCTION

In a 31 Jul 1995 memorandum entitled "Visual Enhancements for USAF Aviators" (Ref 1), the Air Force Chief of Staff directed the Aerospace Ophthalmology Branch at the Armstrong Laboratory [now the U.S. Air Force School of Aerospace Medicine (USAFSAM)], Brooks Air Force Base (AFB), TX, to devise tests that could detect the complications of the then novel surgical procedure of photorefractive keratectomy (PRK). The intent was to evaluate the potential safety and effectiveness of PRK surgery for USAF aviators and develop new aeromedical standards for Undergraduate Flying Training applicants. Aeromedical standards for operational flying are inherently different than traditional clinical criteria used by the civilian ophthalmic community. Minor visual problems that are considered to be inconsequential for most civilians may become potentially life threatening when flying in unique and often hostile military environments that include the following: nighttime, mesopic, or all-weather conditions;

temperature extremes; altitudinal hypoxia with potential for rapid decompression; G-forces; excessive vibration; wind shear and ejection situations; laser and other directed energy effects; and multi-sensor night vision devices. Because Air Force pilots and aviators are extremely valuable resources, their health, safety, and mission effectiveness require constant vigilance. The Aerospace Ophthalmology Branch at USAFSAM functions as the sentinel to ensure that aircrew performance remains optimized as new technologies emerge and are considered for eventual military applications. Accordingly, a comprehensive scientific investigation was initiated to thoroughly and accurately evaluate visual performance post-PRK with emphasis on detecting complications and quality of vision (QoV) issues. This study, as one part of the extensive investigation, was designed to precisely measure high- and low-contrast visual acuity and post-PRK residual refractive errors. Multiple tests of high- and low-contrast visual acuity, including distance and near vision charts, and manifest and cycloplegic measures of refractive error were conducted to detect and evaluate any negative effects from PRK that might potentially degrade operational performance.

Table 1 dispels the myth that Air Force pilots are required to have perfect uncorrected vision. As shown, the USAF has experienced an increasingly larger proportion of its aviator population requiring corrective lenses for flying duties (Ref 2-5). As seen in the 1995 study, an astonishingly high percentage (39.4%) of pilots required optical correction in the form of glasses or contact lenses. An earlier study in 1981 (Ref 6) of 534 U.S. Air Force Academy (USAFA) graduates revealed that 36.3% of applicants required corrective lenses on entry into Undergraduate Pilot Training (UPT). Similarly, other research studies reported on refractive errors in the USAFA class of 1985 (Ref 7,8). These studies documented a clinically significant myopic shift (defined as -0.50 diopter (D) or greater) from entrance to the third academic year in 21.3%, 25.0%, and 55.1%, respectively, of those classified at entry as hyperopes, emmetropes, or myopes. In addition, a progressive increase in myopia was found in those with higher refractive errors at entry. The papers concluded that young myopic adults are not immune from progressive changes, particularly those engaged in intensive educational programs. Table 2 displays data from a 1990 study (Ref 9) of USAF pilots by mode of entry that show a distinct increase in spectacle wear over time, especially for those pilots who had attended the USAFA. This trend is expected to continue in the future as a consequence of the more liberal aeromedical standards for entry into UPT for visual acuity and refractive error adopted over the last 20 years. Table 3 reviews the gradual relaxation in USAF policy governing entry criteria for medical waiver and exception-to-policy cases regarding myopia. A conclusion from these studies was that aircrew candidates who enter UPT with minus or plano refractive values were much more susceptible to develop myopia during their flying careers than those with plus refractive values.

Table 1. Incidence of Spectacle Wear by Survey in Trained USAF Pilots, Navigators/Weapons System Operators (Navs/WSOs), and Other Aircrew from Four Previous Studies (Ref 2-5)

| Group | Incidence (%) for Survey Year-- | | | |
|---------------|---------------------------------|-----------------|------|-------------------|
| | 1969 | 1980 | 1990 | 1995 |
| Pilots | 17.0 | 19.6 | 27.4 | 39.4 |
| Navs/WSOs | 29.0 | 50.0 | 51.5 | 63.6 |
| Other Aircrew | NA ^a | NA ^a | 40.2 | 78.0 ^b |

^aNA = no available data.

^bOnly flight surgeons were surveyed.

Table 2. Incidence from a 1990 Study (Ref 4) of Spectacle Wear Over Time for a Sample of Pilots by Mode of Entry into the Air Force

| Data Point ^a | Incidence (%) for Entry Mode-- | | |
|-------------------------|--------------------------------|------------------------------|---------------------------|
| | USAFA (N=876) | AFROTC ^b (N=1203) | OTS ^c (N=1010) |
| Entry | 8.6 | 4.8 | 4.7 |
| UPT | 33.3 | 7.7 | 7.5 |
| Trained | 37.7 | 22.9 | 24.2 |

^aEntry = initial entry on active duty; UPT = start of Undergraduate Pilot Training; Trained = most recent eye examination as a trained pilot.

^bAir Force Reserve Officer Training Corps.

^cOfficer Training School.

Table 3. Historical Review of Changes Over Time in Air Force Aeromedical Vision Standards for Myopia in UPT Applicants

| Applicants | Myopia ^a (D) | Uncorrected VA ^b |
|-----------------|-------------------------|-----------------------------|
| Pre-1975 | | |
| All | -0.25 | 20/20 |
| 1975 | | |
| OTS/AFROTC | -0.25 | 20/20 |
| USAFA | -1.25 | 20/50 |
| 1980 | | |
| OTS | -0.25 | 20/20 |
| USAFA/AFROTC | -1.25 | 20/50 |
| 1990 | | |
| OTS | -0.25 | 20/20 |
| USAFA/AFROTC | -1.50 | 20/70 |
| 1996 | | |
| All | -1.50 | 20/70 |

^aIndicates maximum allowed minus (in diopters) in any ocular meridian on cycloplegic refraction.

^bIndicates the minimal uncorrected visual acuity required in each eye.

Optical correction, i.e., eyeglasses or contact lenses, has worked relatively well over the years for Air Force aviators to correct manifest refractive errors. On the other hand, spectacle frames and lenses have inherent compatibility problems with certain avionics and basic life support equipment, such as flight helmets, visors, oxygen masks, and chemical/biological defense gear (Ref 10). Although compatibility issues have been greatly reduced with the new USAF aircrew flight frame, problems still remain, especially with night vision goggles (NVGs), modern helmet-mounted displays, thermal sensors, and targeting devices that compromise space requirements in front of the eyes. Soft contact lenses, which were approved for USAF aircrew use in the early 1990s after extensive testing (Ref 11), provided an effective alternative to eyeglasses. Unfortunately, ametropic aircrew cannot always wear soft contact lenses comfortably or achieve good vision. In some instances, corneal health is compromised (Ref 12). Corneal refractive surgery (CRS), specifically PRK, now offers the aviator a potentially viable alternative to reduce dependence on both spectacles and contact lenses (Ref 13). In general, CRS has attained a great deal of success in the civilian community; however, consistent reports about QoV problems after surgical procedures have emerged (Ref 14-21). The USAF maintains great interest in these reports because any reduction in visual performance, no matter how subtle, could seriously impact mission safety and operational performance in a potentially large number of flying personnel eligible for PRK.

Photorefractive keratectomy involves using an ultraviolet-C laser at 193 nm to physically remove layers of cornea to create a central flattened corneal zone. For myopic treatments, this reduces the light-bending capability of the cornea and moves the preoperative intraocular point of focus back from well in front of the retinal surface to closer to the retinal focal plane as intended postoperatively. By doing this, the magnitude of the optical corrective requirements for an eye can be reduced or eliminated, thus reducing dependence on optical appliances. The laser, referred to as the excimer laser, an acronym for “excited dimer” of the argon-fluoride excitable material used in the laser, achieves its tissue effects through photochemical, thermal, and acoustical molecular mechanisms that result in actual vaporization of the targeted corneal tissue. Before lasers can effectively ablate deeper corneal tissue, the corneal epithelium must be removed first. The laser then vaporizes Bowman’s layer and up to 10% of the anterior corneal stroma, depending on the amount of preoperative refractive error to be corrected. This surgical trauma induces a histopathological response in the remaining corneal tissue characterized by a process that induces corneal haze and scarring. Post-PRK corneal haze is usually transitory and short-lived. In previous studies (Ref 13-18), however, some longer lasting corneal haze and scarring developed, which resulted in visual/optical side effects that reduced QoV.

Many studies (Ref 17-24) have reported that, even though high-contrast visual acuity (VA) was often relatively normal after PRK, night vision and low-contrast VA were reduced. An early report from the United Kingdom (Ref 25) described a normal postoperative recovery sequence following PRK surgery as follows: poor vision for at least 1 week; watery vision for 1 month with significantly reduced contrast sensitivity; haze for 1 to 3 months, although possibly more persistent; stabilization usually by 6 months but reduced contrast sensitivity for 6 to 12 months. A subsequent study (Ref 14), which employed smaller surgical ablation zones, quantified the mean reduction in low-contrast VA to be over 1½ lines of letters at 1 year post-PRK. A more recent study (Ref 18) found that visual performance as tested with the Rabin Small Letter Low Contrast chart had not returned to pre-PRK normal in 81% of eyes at approximately 1 year post-PRK. Another study (Ref 20) that used an intra-subject design reported that post-PRK corrected VA was reduced in the treated eye, as compared to the untreated fellow eye, with

the greatest difference found under conditions of low contrast and/or low illumination. These issues have driven a major paradigm shift in terms of how to define success, both clinically and occupationally, after corneal refractive surgery.

Another significant issue is that postsurgical testing in typical civilian clinical settings often tends to grossly underestimate the existence of subtle QoV problems. This arises because traditional photopic high contrast “20/20” eyechart testing, although inherently limited, is the generally accepted standard despite the fact that in multiple studies nearly 98% of aircrew and aircrew application are better than 20/20. However, the efficacy of this 20/20 standard based on testing only high-contrast visual acuity is currently being questioned because it may miss very significant reductions in night or low-contrast vision that are present. In fact, the deficiency of the 20/20 standard has been stressed in multiple studies (Ref 24-30) that reported greater degradations in low-contrast VA than in standard high-contrast VA, even when subjects were given their best postsurgical optical correction. These points were emphasized by a special advisory panel of subject-matter vision experts convened by the U.S. Army as part of its investigation of CRS (Ref 31). In addition, some patients do not recognize potentially significant effects on visual performance in their daily lives (Ref 32). Even long-term impairment of low-contrast vision, mesopic contrast sensitivity (CS), and/or glare disability may go undetected because individuals may not drive much at night or work under the precise conditions that would make it recognizable. What remains unequivocal, however, is that a certain percentage of patients, after undergoing CRS, will have significant low-contrast visual disturbances resulting from decreased CS, glare disability, and image degradation (Ref 17). Consequently, this has generated a major paradigm shift within the civilian sector that has sensitized practitioners to these issues and their impact on QoV. These post-CRS issues, of course, translate into potentially significant concerns for military occupations that rely on optimal visual performance in impoverished visual conditions, such as all-weather, round-the-clock flight operations; low light; or when using artificial night sensors like NVGs, thermal imagers, or forward looking infrared (FLIR) systems.

There are several potential causative factors for QoV problems post-PRK. A new test being evaluated to assess pilot vision in the United Kingdom (Ref 33) found that visual performance may be reduced in some subjects because of degraded retinal image quality from increased optical aberrations and scattered light after refractive surgery. Degraded retinal image quality can also be caused by the presence of subepithelial corneal haze (more likely after PRK than other types of CRS); corneal topographical irregularities, such as irregular astigmatism; and higher order wavefront optical aberrations that are either unmasked or induced by CRS. In some cases, eliminating higher order optical aberrations may not be a good thing. Corneal irregular astigmatism and wavefront aberrations post-CRS often have a significant negative correlation with contrast sensitivity performance (Ref 20,34). Custom corneal ablations with wavefront-guided treatment for CRS were designed to correct some higher order optical aberrations (Ref 35). However, custom PRK was not approved by the Federal Drug Administration (FDA) at the time of this study. Although off-label use of custom wavefront-guided treatments has demonstrated potential for reducing some QoV problems, early custom-ablation LASIK studies do not identify a significant long-term benefit at this juncture. In the future, custom wavefront-guided surgery (Ref 23) may routinely be used to solve many of the QoV problems that degrade low-contrast VA and night vision performance under low light conditions after CRS. Arguably, there is still much to learn about higher order aberrations, particularly their role in visual performance, and how to adjust for them with CRS. Until that time, however, the USAF must

continue to monitor QoV issues after PRK and remain intensely vigilant regarding CRS procedures. The bottom line is that any reduction in visual performance, especially in low-contrast or night vision situations, could have disastrous consequences on the ability to maintain a safe and effective fighting force in what may evolve into an increasingly large number of military aviators that have had CRS.

The potential for quality of vision consequences from PRK is of concern for USAF pilots and aviators, especially when flying at night, in bad weather, or with NVGs. Although acceptable levels of high-contrast Snellen acuity can often be achieved that may reduce or eliminate spectacles or contact lenses during the day, post-PRK QoV across the operational range of low-contrast and reduced illumination may be critically affected and go undetected by traditional high-contrast letter acuity tests. In addition to post-PRK QoV, mission and aeromedical concerns after PRK include the complicating parameters of altitude; gravitational forces; effects from broadband and/or laser glare; and night, mesopic, or NVG operations. Unfortunately, there was very little published literature that addressed pertinent aeromedical issues prior to the USAF PRK Study (Ref 13). Consequently, an extensive scientific study of post-PRK performance was needed to investigate potential aeromedical and operational concerns. Accordingly, the USAF PRK Study was designed to be an initial effort to focus on those aeromedical issues and comprehensively evaluate pre- and postsurgical visual function over 24 months duration after PRK. It included precise measurements of the following: photopic high-contrast VA at distance and near, low-contrast VA for multiple spatial frequencies, manifest and cycloplegic refractive errors, mesopic low-contrast night vision with and without glare, NVG performance at two ambient light levels, effects of altitude and G-forces, glare effects in the cockpit from laser and broadband sources, electronic contrast sensitivity, and complications in corneal physiology. Earlier publications of other segments of the comprehensive USAF PRK Study have reported the data on nighttime cockpit glare (Ref 36,37), high +Gz effects of altitude (Ref 38), and mesopic night vision and NVG performance (Ref 39). This endeavor represents the next piece in the sequential publication of the remaining data from the full study. It employs a prospective experimental design to compare pre-PRK corrected performance to post-PRK performance, both corrected and uncorrected, in terms of high- and low-contrast visual acuity and residual refractive errors.

3.0 PURPOSE

The USAF Photorefractive Keratectomy Study was designed to be a prospective study of the aeromedical applicability of this surgical procedure. The purpose of this part of that comprehensive study was to accurately measure photopic distance and near visual acuity, using both high- and low-contrast eye charts, and to precisely assess refractive error before and after PRK. The primary goal was to detect and identify any changes, no matter how subtle, in normal visual function that may have been induced by PRK surgery or its sequela that could negatively affect operational flying performance. Also, the data will be used to help determine if new aeromedical vision standards, or more sensitive vision screening tests, would be required to adequately evaluate subtle quality of vision issues in post-CRS aviator candidates before allowing them to attend flight training. The emphasis on aviation candidates underscores a significant constraint in the USAF PRK Study design. It originally was devised as an evaluation to support selection policy for UPT applicants who had undergone PRK. It was not intended to be a return-to-fly study for trained aviators following PRK. Consequently, additional follow-on

studies were planned as part of a full research program to more thoroughly evaluate the efficacy of PRK, and all CRS, for broader adoption into trained USAF aviation populations.

4.0 METHODS

The USAF PRK Study was commissioned by the AF Chief of Staff, General Ronald Fogleman, in Jul 1995. An unexpected reorganization of the Air Force Research Laboratory (AFRL) at Brooks delayed the project start for over 2 years. Recruitment of subjects began in Jun 1998 once funding lines were secured and following approval of the experimental protocol by the appropriate institutional review boards (IRBs). A prospective experimental design finally was adopted to evaluate the subject population that was carefully selected to match the visual attributes of USAF aviators. A longitudinal design was used that called for a 2-year duration study extending from baseline (pre-PRK) to 24 months post-PRK. All pre- and postoperative visual and physiological function testing was conducted at Brooks AFB, TX, per the study protocol as approved by the Brooks Institutional Review Board (IRB #98-F-BR-0016-H). All PRK surgery and surgical follow-up was performed by a single surgeon at the Laser Refractive Surgery Center in the Ophthalmology Department at Wilford Hall Medical Center (WHMC), Lackland AFB, TX, per the approved surgical protocol IRB- SGO #95-183 (25 Apr 1995) as revised on 25 Mar 1997. A total of 375 nonflying active duty USAF members, including officers and enlisted, was initially screened for inclusion. Of those, 276 were disqualified for various ocular, medical, or surgical conditions. The remaining 99 subjects were admitted to the study, but 20 served as controls and did not undergo PRK surgery until after the study was completed. All study members underwent a comprehensive array of ocular, visual acuity, and visual performance tests to establish baselines, including measurement of cycloplegic and manifest refractive errors. All data were collected at the Aerospace Ophthalmology Branch in the Clinical Sciences Division of the USAF School of Aerospace Medicine in partnership with AFRL at Brooks AFB. The surgery was performed at WHMC as was all postoperative care until the acute healing phase was complete, generally about 7-8 days after PRK. At Brooks AFB, TX, subjects had to complete periodic comprehensive and specialized testing sessions lasting 1-3 days over the 24-month duration of the study. The data acquisition phase of the study was concluded on 1 Jun 2002.

4.1 Subjects

The subject population was carefully selected to match the visual attributes of USAF aviators. One hundred nonflying active duty USAF personnel were initially chosen from a large pool of volunteers to be subjects for this study and to undergo PRK corneal refractive surgery (one subject was lost to transfer before having surgery). As part of the selection process, all subjects were required to undergo a full-dilated ocular examination and comprehensive vision screening in the Aerospace Ophthalmology Branch at the USAF School of Aerospace Medicine, Brooks AFB, TX. The primary criteria for subject selection were Flying Class III aeromedical vision standards per Air Force Instruction (AFI) 48-123, *Aerospace Medicine: Medical Examinations and Standards*. Additionally, each subject had to pass a rigorous presurgical screening for selection based on an extensive preoperative workup and a lengthy questionnaire, which served to eliminate subjects with contraindications for PRK in accordance with established FDA study criteria and projected policy requirements. The previously listed IRB

protocols were strictly followed, and voluntary informed consent was obtained on all subjects as required in the IRB protocols and AFI 40-402. Specific selection criteria and subject demographics are provided in companion publications related to the USAF PRK Study.

Of the subjects selected, 20 were used as controls and 80 were chosen to receive PRK treatment (controls received PRK after completing their 24-month evaluations). After making the final selection, 79 patients or 158 eyes were evaluated and followed after treatment within the USAF PRK Study protocol. As shown in Table 4, the mean presurgical spherical equivalent values for refractive errors treated in this study were -3.26 (+/-1.45) D for the right eye (range: -1.00 to -6.75 D) and -3.22 (+/-1.40) D for the left eye (range: -1.00 to -7.00 D), based on cycloplegic examinations. The presurgical magnitude of astigmatism was essentially limited to cylindrical powers of 1.00 D or less to simulate the pilot population and to eliminate any problems solely related to the correction of high astigmatic refractive errors.

Table 4. Baseline Cycloplegic Refractive Error for OD and OS in All 99 Study Subjects (Controls and Treated) Showing Means and Standard Deviations (SDs) for Spherical Equivalent Power and Cylinder Power to Correct Astigmatism

| Eye | Spherical Equivalent (D) | | Astigmatism (D) | |
|-----|--------------------------|-------|-----------------|-------|
| | Mean | SD | Mean | SD |
| OD | -3.26 | ±1.45 | 0.49 | ±0.35 |
| OS | -3.22 | ±1.40 | 0.47 | ±0.36 |

The treated group was further divided into four subgroupings of 20 subjects each for laboratory testing. These separate study groups were created within the treated subject pool to evaluate post-PRK effects on simulated operational performance. The four laboratory subgroupings were human centrifuge study group, altitude chamber study group, cockpit environment study group, and a treated control group that did not participate in any laboratory performance testing. Because the laboratory tests required exposure to centrifugal force, high altitude, or bright glare from a laser, the refraction and visual acuity testing reported here was always completed before these additional challenges were conducted. Data from the simulated operational performance testing in the individual laboratory subgroups are reported in companion USAFSAM technical reports (Ref 36,39).

This prospective study required data collection on subjects at regular intervals. Initial readings were accomplished to obtain baseline values and subsequently at set intervals over a 24-month time period post-PRK surgery, or postbaseline reading for untreated controls. Limitations in the surgical schedule precluded doing all the PRK surgeries at the same time; in addition, some subjects had their right and left eyes treated several weeks apart. As a consequence, a total of 42 months was required to totally complete the data collection on all subjects.

As mentioned, this effort to evaluate visual acuity and refractive error was part of a much larger comprehensive study of post-PRK visual function that included many other performance tests, both visual and operational. Because of the lengthy experimental follow-up schedule, USAF personnel actions, operational exigencies, and the requirement for many subjects to

continue to participate in uncomfortable laboratory tests, e.g., rides in the human centrifuge, ascents in the altitude chamber, or testing in the simulated cockpit with bright laser or broadband glare, some subjects did not complete all follow-up exams. This attrition prevented consistency in the number of subjects, or eyes, seen at each of the follow-up points for statistical analysis, so that the total subject/eye count differed for each session. Also, it should be noted that the monocular and binocular data sometimes varied in number because some subjects had their right and left eyes treated several months apart. Obviously, this precluded having binocular test data at the first follow-up visit for everyone. In addition, not all testing was conducted at the 1-month and 4-month post-PRK follow-up evaluations because of patient schedules and time constraints, especially since most study subjects were required to participate in lengthy testing in the human centrifuge, altitude chamber, or cockpit simulator. In hindsight, this is now considered to be a regrettable omission because the early post-PRK data would have been invaluable in developing return-to-cockpit criteria for trained aviators after PRK. Since this was designed to be a selection-based study only, complete evaluations earlier than 4 months post-PRK were not included. However, full evaluations were conducted out to 24 months post-PRK to provide relatively long-term data from the broad sample of carefully selected subjects.

4.2 Surgical Protocol

The following provides a summary of the strict PRK treatment protocol including pre- and postsurgical management procedures. All PRK surgical procedures were performed by a single surgeon at Wilford Hall Medical Center using a VISX Star, 193-nm, argon fluoride, broad-beam excimer laser (Ref 23). After undergoing an extensive preoperative workup and questionnaire, patients with contraindications for PRK were eliminated in accordance with established FDA study criteria. Accordingly, 80 patients or 160 eyes were selected for the study. Stringent uniform presurgical and surgical procedures were followed as indicated. The periorbita of the preoperative eye was prepped with 10% povidone-iodine. Preoperative eye drops of ofloxacin 0.3% (Ocuflox), diclofenac 0.1% (Voltaren), and tetracaine 0.5% were used immediately prior to the laser procedure. The entire laser procedure was centered over the entrance pupil. The corneal epithelium was removed using a 42-micron "laser scrape" technique with any residual epithelial cells and debris being removed afterwards with a blunt spatula. Thereafter, any remaining cells, debris, or excess fluid in the treatment zone were then removed with a Merocel eye spear. These steps were followed with another pass of a chilled, balanced, saline-moistened Merocel eye spear just prior to beginning the actual treatment ablation. A 6.0-mm ablation zone and a pulse rate of 6.0 Hz using a VISX Star excimer laser were used for all PRK surgeries. Immediately after the procedure, 5 cc of chilled balanced saline was used to rinse the ablation zone. Only one eye was treated at each setting; at least 1 month of healing time was allowed before the other eye was surgically treated. Postoperatively, all patients were fitted with bandage soft contact lenses until complete re-epithelialization of the cornea was confirmed. This usually occurred by postoperative day 3 or 4. The patients were also placed on ofloxacin 0.3% three times/day for 1 week, diclofenac 0.1% two times/day for 1 to 2 days, and celluvisc (preservative-free artificial tears) four times/day. The topical steroid fluorometholone 0.1% was used in a standardized tapering dose of four times/day for the first month, three times/day for the second month, two times/day for the third month, and one time/day for the fourth month. The intraocular pressure was closely monitored during the steroid taper. Clinical postoperative

follow-up was done daily until re-epithelialization occurred, then at 1 week and 1, 2, 3, 4, 6, 12, 18, and 24 months after surgery.

4.3 Measurement of Refraction

The tests to assess refractive error employed in this study were (1) objective measures including traditional static retinoscopy and/or automated refractometry (Nidek ARK-700A Auto Refractometer/Keratometer by Marco) and (2) subjective measures using automated phorometry (Nidek RT-2100 Refractor by Marco) or a standard Reichert phoropter. Both manifest and cycloplegic (dilated) refractions were conducted on each subject at every evaluation time. A strict protocol was followed for performing cycloplegic refractions based on directives in AFI 48-123, which specifies the following: instill one drop of Ophthaine; instill one drop of 1% Cyclogel; instill another drop of 1% Cyclogel after waiting 5 minutes; start the refraction approximately 45 minutes after the last drop, but no later than 100 minutes after.

4.4 Visual Acuity Test Battery

A high-contrast Snellen letter eyechart is the standard test used to measure visual acuity during most clinical eye examinations. It usually contains a series of letters or numbers that become progressively smaller proceeding down the chart. The Snellen fractions, 20/20, 20/30, etc., relate to the ability to identify an optotype, usually a letter, of a certain size from a specified distance. However, statistical analysis and calculations based on the fractions used in standard clinical eyecharts may seem puzzling and imprecise. Early studies that used Snellen fractions often provided confusing results due to the inherent inadequacies of this type of visual acuity test. For example, most Snellen visual acuity tests have differing numbers of letters per row, e.g., 10 letters on the 20/20 line, but only 3 letters on the 20/70 line. Therefore, if the results of a study showed that the patients “gained three letters of acuity,” the results could indicate the gain of a full acuity line, as in the 20/70 line, or only a portion of an acuity line, as in the 20/20 line. Also, the individual lines on the Snellen acuity test are not equally spaced. For example, the change from the 20/25 line to the 20/20 line is a 20% change, while the change from the 20/30 line to the 20/25 line is a 16% change. In addition, if a study demonstrated a two-line increase in acuity, it could mean a 33% improvement from 20/30 to 20/20 or a 40% improvement from 20/50 to 20/30. Other inadequacies also exist in testing with a standard Snellen chart including the types of letters used on the test, spacing of the letters, and the lack of a standard calibrated luminance. Therefore, the many deficiencies in Snellen VA testing made it impractical to accurately evaluate subtle changes in visual performance and to compare data from study to study.

As a result, new visual acuity test charts were developed in the past that could more accurately evaluate changes in vision from study to study and over time. In 1982, the National Eye Institute, National Institutes of Health, developed a new VA chart series that was based on a hybrid design. The charts were designated ETDRS, which stands for Early Treatment of Diabetic Retinopathy Study, because they were originally used to evaluate the short- and long-term effects of pan-retinal photocoagulation in patients with diabetic retinopathy. A typical ETDRS chart has letter sizes that follow a standard logarithmic progression in terms of LogMAR. LogMAR is an acronym for \log_{10} of the minimum angle of resolution (MAR). The MAR is the width of the detail of the smallest visible letter, i.e., a 20/20 letter subtends 5 minutes of arc overall, but the

detail (stroke width) equates to a MAR of 1 minute of arc. In general, logMAR is the most precise research method for quantifying VA and performing statistical analysis.

Several types of ETDRS eyecharts were used in this study to measure photopic visual acuity and low-contrast vision. The specific battery that was employed included the following eyecharts: ETDRS Near, ETDRS Distance, Bailey-Lovie (B-L) Low Contrast, and Rabin Small Letter Contrast Test (SLCT). In addition, visual acuity measures were recorded on the Armed Forces Optec 2300 Vision Tester (OVT) for comparison purposes, but only at the 24-month evaluation. Post-PRK performance with these eyecharts was measured both uncorrected and with best correction in a trial frame for oculus dexter (OD), oculus sinister (OS), and oculus uterque (OU). Testing was done at baseline and then at 1, 4, 6, 12, and 24 months after baseline or postsurgery. Best-corrected performance was tested on all charts at the pre-PRK baseline evaluation; however, the ETDRS Distance VA chart was the only chart used to measure uncorrected VA at baseline. In addition, VA testing was conducted after the cycloplegic refraction using the distance ETDRS and Bailey-Lovie low-contrast charts. This provided a measure of high- and low-contrast VA with wide pupillary dilation. Postcycloplegia testing was always done with best correction in place to isolate any changes induced by the transition in the surgical ablation zone or from a decentered ablation.

4.5 Distance and Near ETDRS Charts

The Distance and Near ETDRS tests employed similar charts that were properly scaled for the difference in testing distance, 20 feet (6 meters) versus 18 inches, and were designed for accurate measurements of small changes in visual acuity. The ETDRS charts were used because standard Snellen charts may not provide sufficiently accurate, nor repeatable, information regarding subtle changes in visual function. The ETDRS type of chart used in this study, and shown in Figure 1, is considered to be the gold standard for measuring visual acuity for clinical research purposes. These charts have some unique features: (1) each line has five letters, so there is an equal opportunity to make an error on each line; (2) the letters have been selected so that there is an equal probability for error in reading them, e.g., the letter “I” does not appear because it is rarely misread; (3) the letter sizes change from row to row in a standard geometric progression; (4) ETDRS letters are all square, e.g., 20/20 letters are 5 minutes of arc in height by 5 minutes of arc in width; and (5) a standardized illumination level of 224 candela per square meter (cd/m^2) is required for all testing. To eliminate chart memorization, three different ETDRS configurations (Charts R, 1, and 2) were used. Listed on the right-hand side of the chart is the Snellen equivalent visual acuity calibrated for testing done at 20 feet. The ETDRS charts use a logarithmic progression in letter size to measure and record logMAR acuity. Each row of letters changes in size by 1.26x, or 26%, or 0.1 log unit. With five letters per row, each letter equates to 0.1 divided by 5 or 0.02 log units per letter. Precision is increased by carefully tracking the number of letters read correctly and computing VA based on 0.02 log units per letter. Therefore, the size of the confidence interval for normal VA is decreased, which provides greater sensitivity to minor changes.

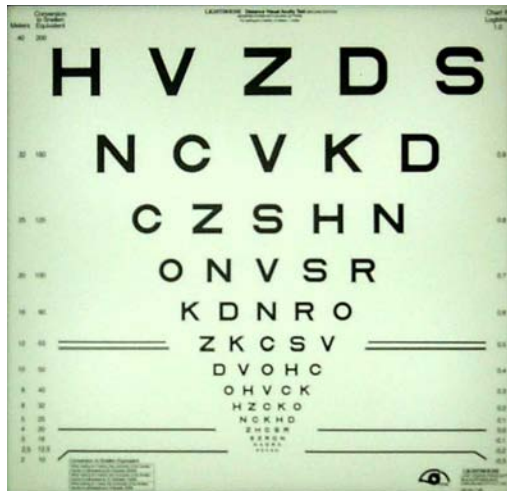


Figure 1. Early Treatment of Diabetic Retinopathy Study (ETDRS) Eyechart Used to Test High-Contrast Visual Acuity

4.6 Bailey-Lovie Low-Contrast Chart

The Bailey-Lovie (B-L) chart is an ETDRS type of logMAR acuity chart that was originally developed by Drs. Ian Bailey and Jan Lovie in 1976 at the National Vision Research Institute, Melbourne, Australia. The B-L chart is similar to several other commonly used ETDRS letter charts including the Regan, Pelli-Robson, Precision Vision series, etc. (Ref 40). The B-L chart used in this study is shown in Figure 2. It is a commercially available, low-contrast version (it also comes in a high-contrast version). Illumination for the B-L chart was maintained by means of overhead fluorescent lighting that provided 92 cd/m^2 uniformly spread over the chart. It is a well-designed letter chart with each line logarithmically scaled in size. The low-contrast version used in this study is listed as a 10% contrast chart. However, on-site laboratory measurements for calibration purposes revealed the particular chart and lighting system used for this study to be essentially 11% contrast (Michelson) or 18% contrast (Weber). This low-contrast B-L eyechart provides accurate visual acuity in terms of logMAR (Ref 41). It is designed to provide the logarithm of the minimum angle of resolution (logMAR) using five letters per line and equal (0.10 logMAR) steps between lines. Visual acuity was measured by counting the total number of letters correctly read and calculating the logMAR, which can be easily done because the number of letters correctly read is directly proportional to logMAR VA. Unlike standard ETDRS charts, the Bailey-Lovie chart incorporates the European design for logMAR, i.e., it uses letter sizes that are rectangular; for example, a 20/20 letter is 4 minutes of arc in height by 5 minutes of arc in width.

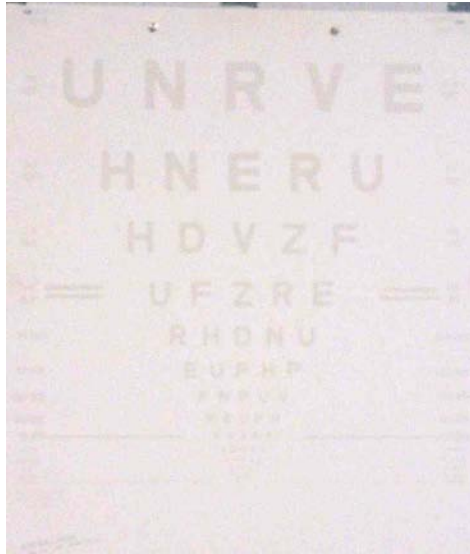


Figure 2. Bailey Lovie (B-L) 10% Low-Contrast Test Chart

The advantages of using the Bailey-Lovie and, similarly, the ETDRS charts are as follows:

- Letter detail, also known as minimum angle of resolution, is 1/5th of the letter height.
- There is a constant number of letters per row.
- Only 10 different letters are used and each is approximately equal in legibility to the others.
- There is a logarithmic progression in letter size (each row changes in size by 1.26x, or 26%, or 0.1 log unit).
- There are five letters per row, so each letter is worth $0.1 \div 5$ or 0.02 log units per letter.
- Precision and sensitivity are increased by assigning 0.02 log units per letter and carefully monitoring the total number of letters read correctly.
- A simple rule can be used to quickly calculate logMAR: e.g., for 20/20 the log of 1 minute of arc = 0; add 0.3 for each 2x increase in letter size.
- Subtract 0.3 for each 2x decrease in letter size (example.g., 20/40 is logMAR of 0.3; 20/10 is logMAR of -0.3).

The actual scoring of the B-L letter chart simply required a count of the total number of letters read correctly for OD, OS, and OU. As discussed, the number of letters correct was directly proportional to logMAR and could be easily converted to Snellen visual acuity. For example, at a test distance of 20 feet, reading 30 letters correct is equal to a logMAR of 0.30, which computes to 20/40 Snellen VA. LogMAR values, calculated from the number of letters correct, were used for all computations and statistical analyses and eventually converted to Snellen VA for graphical display.

4.7 Rabin Small Letter Contrast Test

The measurement of low-contrast vision was accomplished by using the Rabin Small Letter Contrast Test (SLCT) chart, which provided a measure of low-contrast VA under photopic

lighting conditions for a high spatial frequency target. The SLCT chart, shown in Figure 3 (Ref 42), was designed by Jeff Rabin, OD, Ph.D., a U.S. Army vision scientist, to provide a sensitive measure of visual capabilities in applicants for military aviation, especially those candidates who had undergone CRS. The Rabin SLCT measures visual performance at one letter size, or spatial frequency, across a wide range of contrast levels. The letter size is equivalent to 20/25 Snellen VA; the detail in each letter subtends 1.25 minutes of arc at the testing distance of 4 meters.



Figure 3. Rabin Small Letter Contrast Test (SLCT) Chart

The Rabin SLCT chart consists of 14 lines of letters with 10 letters per line. Each successive line going down the chart uniformly decreases in contrast by 0.1 log units and increases in contrast sensitivity by 0.1 log CS steps. Accordingly, each letter is equivalent to 0.01 log CS. The scores for number of letters correct can easily be converted to relative log CS values by multiplying by 0.01 and then subtracting 0.1; e.g., a score of 63 letters correct is equivalent to 0.53 log CS. Illumination for the SLCT chart was maintained by means of overhead fluorescent lighting that provided 81 cd/m² uniformly spread over the chart. Testing was conducted at each session using a trial frame with best spectacle correction and measuring, using standardized forms, the actual number of letters read to obtain a small letter contrast sensitivity score for OD, OS, and OU. Data collection was performed at baseline (or pre-PRK) and at 1, 4, 6, 12, and 24 months postbaseline or after surgery and subsequently input to a computerized database for statistical workup. Specifically, the Rabin SLCT chart was used to measure contrast sensitivity at photopic light levels for a high spatial frequency, i.e., 20/25 size letters.

4.8 Armed Forces Optec 2300 Vision Tester (OVT)

The Armed Forces Optec 2300 Vision Tester (OVT) (Fig. 4) was also used for testing, but only at the 24-month evaluation. The OVT performs very adequately as a self-contained, portable, pass/fail vision screening device for the USAF, but has limited utility as a research tool. Although OVT testing was not conducted at presurgical baselines or any evaluations during the

first year, the 24-month OVT data were still useful by providing another test to compare post-PRK performance with and without correction. Per USAF aeromedical physical standards (AFI 48-123), the OVT is the required vision screening device at USAF bases worldwide for aviator physical examinations and checkups.

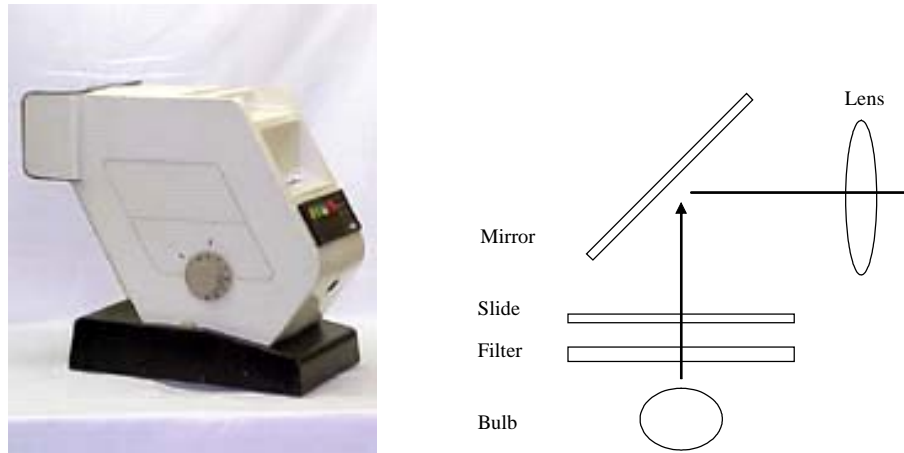


Figure 4. Armed Forces Optec 2300 Vision Tester (OVT) with Schematic Diagram

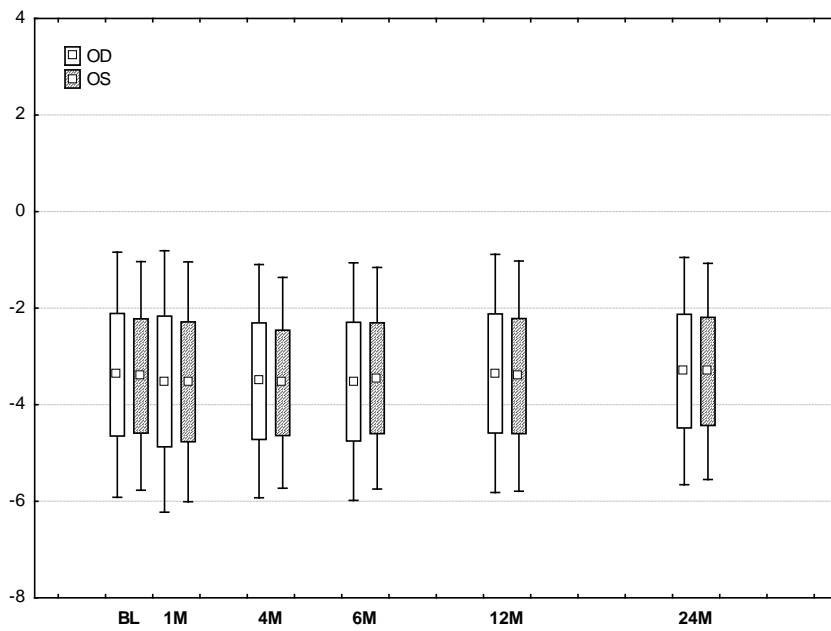
5.0 RESULTS AND DISCUSSION

A prospective experimental design was used to compare post-PRK residual refractive errors and pre-PRK corrected visual performance to post-PRK performance, both corrected and uncorrected, in terms of high- and low-contrast visual acuity (at distance and near). Control group data were also tabulated for refraction and eyechart performance with best optical correction to show variability over time on the various tests. Standard descriptive statistics were used for presenting the results in terms of means and standard deviations; these data are displayed in the tables in the appendices and the figures in this section. The figures in this section also display postsurgery data in terms of visual acuity values and lines of letters lost versus lines gained. For VA analysis, values were always computed in logMAR and then converted to Snellen equivalent values.

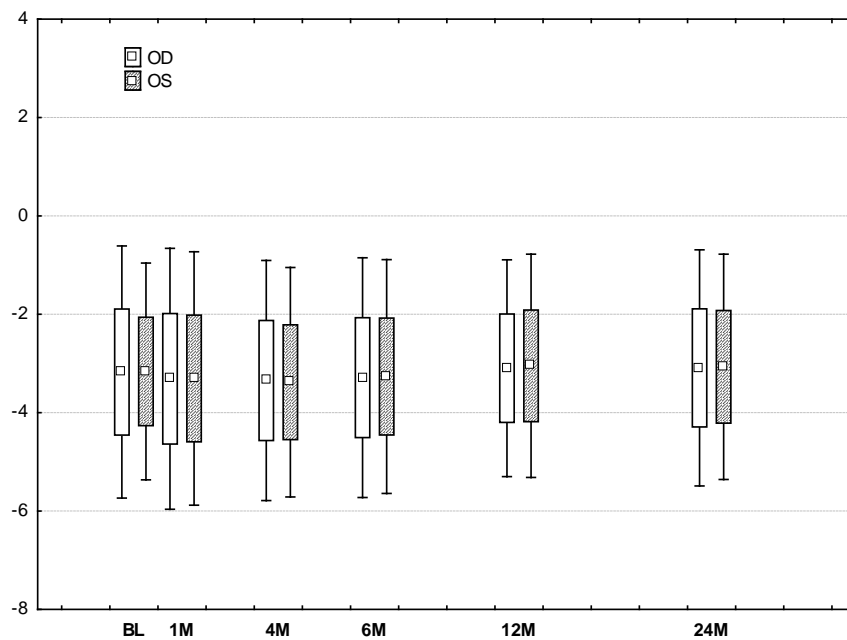
5.1 Refraction

The refractive data, both manifest and cycloplegic, are provided in Appendix A in terms of mean spherical equivalent values over time for the control group (Table A-1) and for the PRK-treated group (Table A-2). The manifest and cycloplegic data are also displayed graphically for controls in Figure 5 and for PRK-treated subjects in Figure 6. The control group data show reasonable stability over 24 months with a slight trend towards decreased myopia consistent with normal age-related changes over time. Typical differences between manifest and cycloplegic examinations can be readily noted, i.e., 0.25-0.50 D of more plus or less minus power is normally found when subjects are examined under full cycloplegia as compared to manifest refraction. The PRK-treated group shows a big reduction in refractive error after PRK surgery, as intended, that is relatively stable but changes in the more minus (myopic) direction over time. This slight increase in myopia from 4 to 24 months post-PRK was not statistically significant.

However, mean values after PRK surgery for manifest refraction can be seen to approach the potentially clinically significant value of -0.50 D of myopia.

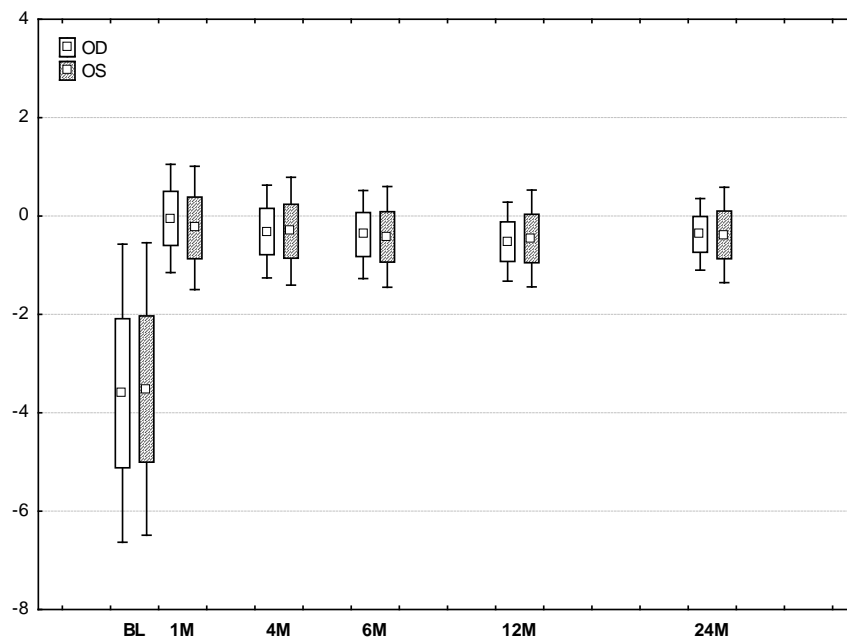


A.

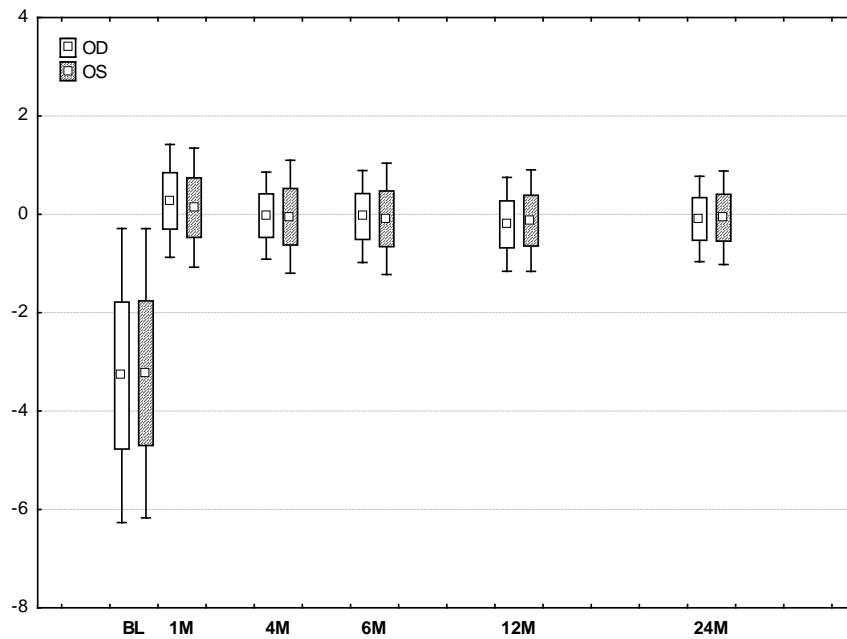


B.

Figure 5. Means and SDs for Control Subjects Plotted at Initial Baseline (BL) and at 1-, 4-, 6-, 12-, and 24-Mo Follow-Up Evaluations for (A) Manifest Refraction and (B) Cycloplegic Refraction (Vertical Scale Represents Spherical Equivalent Power in Diopters)



A.



B.

Figure 6. Means and SDs for PRK-Treated Subjects Plotted at Initial Baseline (BL) and at 1-, 4-, 6-, 12-, and 24-Mo Post-PRK Evaluations for (A) Manifest Refraction and (B) Cycloplegic Refraction (Vertical Scale Represents Spherical Equivalent Power in Diopters)

Table 5 breaks out the prevalence in post-PRK eyes of low to moderate residual refractive errors based on three criteria for spherical equivalent values. As can be seen, relatively high percentages of eyes have at least -0.50 D (spherical equivalent) on cycloplegic refraction and this increases over time to 30.6% of right and 28.2% of left eyes. More significant surgical undercorrection, as represented by -1.00 D or more of postsurgical myopia, affects fewer subjects, but those with this amount of uncorrected refractive error will undoubtedly require optical correction. Surgical overcorrection, which is represented by the percentages that have +1.00 D or more of spherical equivalent hyperopia on cycloplegic refraction, is relatively high at 1 month but decreases in prevalence over time. This would seem to imply that an initial overcorrection early in the post-PRK healing phase, although problematic then, may be desirable in the long term. However, that is not so true for subjects who are near the age of presbyopia where small amounts of plus power (hyperopia) are problematic. On the other hand, small amounts of undercorrection (residual myopia) are probably less desirable because they are more likely to persist and increase over time, especially in young adults, thereby reducing unaided visual acuity and requiring corrective optical eyewear.

Table 5. Percentage of PRK-Treated Subjects Showing Residual Refractive Errors After Surgery (Based on Spherical Equivalent Values in Diopters from Cycloplegic Refractions)

| Eye | Percentage of PRK-Treated Subjects Showing Residual Refractive Errors After-- | | | | |
|--|---|----------------|----------------|-----------------|-----------------|
| | 1 Mo (N=79) | 4 Mo (N=72) | 6 Mo (N=76) | 12 Mo (N=72) | 24 Mo (N=54) |
| Residual Refractive Error ≥ -0.50 D | | | | | |
| OD | 13.9 | 16.4 | 18.9 | 30.6 | 27.8 |
| OS | 17.9 | 25.0 | 25.0 | 28.2 | 24.5 |
| Residual Refractive Error ≥ -1.00 D | | | | | |
| OD | 0.0 | 1.4 | 4.1 | 6.9 | 1.9 |
| OS | 3.8 | 6.9 | 3.9 | 2.8 | 1.9 |
| Residual Refractive Error $\geq +1.00$ D | | | | | |
| OD | 24.1 | 5.5 | 6.8 | 1.4 | 3.7 |
| OS | 17.7 | 8.2 | 9.5 | 5.6 | 7.4 |

Appendix B presents the data for mean values and SDs for astigmatism from cycloplegic measurements of cylinder correction in OD and OS. Good stability can be noted in the control group data in Table B-1 from initial baseline through each follow-up evaluation. In Table B-2, the PRK-treated group of subjects shows a slight mean decrease from baseline at each postoperative follow-up evaluation, eventually being nearly 0.25 D over time.

The percentages of post-PRK eyes with residual astigmatism greater than or equal to 0.75 D are shown in Table 6. Uncorrected astigmatism of 0.75 D or more is often considered to be clinically significant in the civilian community when fitting soft contact lenses. More importantly, it may be operationally significant during night missions, in low-contrast situations, or when flying with NVGs or thermal imaging devices. Favorable effects after PRK are readily noted as the percentages of eyes after surgery having 0.75 D or more of astigmatism decrease

over time. However, approximately 10% of post-PRK eyes still possessed at least that amount of astigmatism at the 2-year follow-up. This percentage is more than what was anticipated considering that the treated subjects were thoroughly prescreened before surgery to eliminate those with presurgical astigmatism greater than 1.00 D.

Table 6. Percentage of Eyes in PRK-Treated Subjects with ≥ 0.75 D of Astigmatism (Cylinder Correction) on Cycloplegic Refraction at Baseline and After Surgery

| Eye | Percentage of Eyes in PRK-Treated Subjects with ≥ 0.75 D of Astigmatism at-- | | | | | |
|-----|---|-------------|-------------|-------------|--------------|--------------|
| | Baseline (N=79) | 1 Mo (N=78) | 4 Mo (N=72) | 6 Mo (N=74) | 12 Mo (N=70) | 24 Mo (N=53) |
| OD | 38 | 23 | 18 | 12 | 13 | 9 |
| OS | 44 | 15 | 7 | 13 | 11 | 11 |

Table 7 shows the prevalence of anisometropia (refractive differences between OD and OS) in PRK-treated eyes at baseline and each postsurgical evaluation. Significant increases in the percentages of anisometropia post-PRK occur at 1 month and even out to 6 months. However, at the 1- and 2-year evaluations, the incidence is essentially back to presurgical baseline values. The point from these data is that, in a small subset during the first months of the post-PRK healing phase, the binocular visual system may not function the same as before surgery even though monocular visual acuity may be adequate in each individual eye. For example, perceptual effects may be induced that affect depth perception, stereopsis, or retinal rivalry (depending on eye dominance); create a Pulfrich stereo phenomenon; or cause a reversal to occur in the anisometric differential between eyes where one eye had the greater myopia before surgery but after surgery the other eye is now more myopic. Therefore, post-PRK recommendations for aviators must emphasize retraining and require a gradual return to full flying duties and solo flight.

Table 7. Incidence of Anisometropia in PRK-Treated Subjects at Baseline and After Surgery

| Difference Between OD and OS ^a (D) | Incidence (%) of Anisometropia in PRK-Treated Subjects at-- | | | | | |
|---|---|-------------|-------------|-------------|--------------|--------------|
| | Baseline (N=79) | 1 Mo (N=78) | 4 Mo (N=72) | 6 Mo (N=74) | 12 Mo (N=70) | 24 Mo (N=53) |
| ≥ 1.00 | 6.3 | 20.5 | 13.9 | 9.2 | 5.6 | 7.6 |
| ≥ 1.50 | 1.3 | 7.7 | 4.2 | 2.6 | 1.4 | 0.0 |
| ≥ 2.00 | 0.0 | 1.3 | 0.0 | 0.0 | 0.0 | 0.0 |

^aCalculated in spherical equivalent values in diopters from manifest refractions.

5.2 Eyechart Testing

Descriptive statistical analysis was performed for each visual acuity test to provide mean and SD values. Appendices C-G display the VA test results in tables that include mean and SD values for each eye and OU. These data reflect well-controlled procedures and very precise

measurements of the absolute number of letters correctly identified on each test (Ref 43). The results shown in the appendices can only be compared in terms of differences in the average total number of letters read correctly. The data were also converted to standard logMAR values for statistical analyses in terms of Snellen equivalent VA (Ref 44) and lines gained vs. lost after PRK. The Snellen VA values shown in the figures in the subsequent sections are based on logMAR values that were converted from the number of letters correctly identified.

As a preface to discussing the results from the eyechart testing, it should be noted that there may be an inherent postsurgical enhancement effect from the relative magnification, or lack of spectacle minification, in the retinal image after PRK as compared to the minified image present with spectacles before PRK at baseline. This magnification effect is intensified with small-letter, low-contrast types of eyecharts, or CS function tests, as compared to standard high-contrast Snellen letter eyecharts (Ref 30,42). The predicted change in VA or CS resulting from correction at the corneal plane can be calculated and quantified. For example, a -4.00-D myopic patient fully corrected with spectacles, compared with PRK surgical correction to near emmetropia, is expected to show an improvement of 0.02 logMAR (1 letter) on high-contrast VA tests. A greater effect can be anticipated with low-contrast charts, like the Rabin SLCT, that is probably closer to 1 line (10 letters) or 0.1 log CS (Ref 45). Due to the increased relative magnification in the retinal image at the corneal plane, a finite beneficial effect from PRK treatment might be reasonably expected when comparing post-PRK VA or CS to best-corrected pre-PRK performance.

5.3 Near ETDRS Chart

The Near ETDRS data are displayed in Appendix C. As shown in Table C-1, the uncorrected near vision in control subjects stayed about the same for the first 4 months and then improved a few letters on average over the final 6-24 months of the testing period. This may indicate a slight trend toward increasing myopia over time, which was not confirmed by the manifest or cycloplegic refraction data in Figure 5. Another possible, but less likely, explanation may be the normal decrease in pupil size with age, which would provide a pinhole effect. On the other hand, the best-corrected data for controls shown in Table C-2 reveal that near VA actually decreased a few letters at 12 months and again at 24 months. Therefore, the most plausible etiology is the normal effects of aging in some control subjects who are presbyopic or approaching presbyopia.

Tables C-3 and C-4 display the corresponding uncorrected and corrected near vision data for the PRK surgically treated subjects. The uncorrected data show, as anticipated, a significant improvement in near vision at our test distances after PRK surgery compared to presurgical uncorrected baselines. This may reflect decreased astigmatism in functional alteration to a more unreadable reading plane in high myopes. After surgery there are only insignificant minor fluctuations over time. Likewise, the best-corrected data in Table C-4 show very good stability over time. Interestingly, the corrected and uncorrected near VA data in treated subjects are remarkably similar over time; they are both a few letters better than the best-corrected control data at 12 and 24 months.

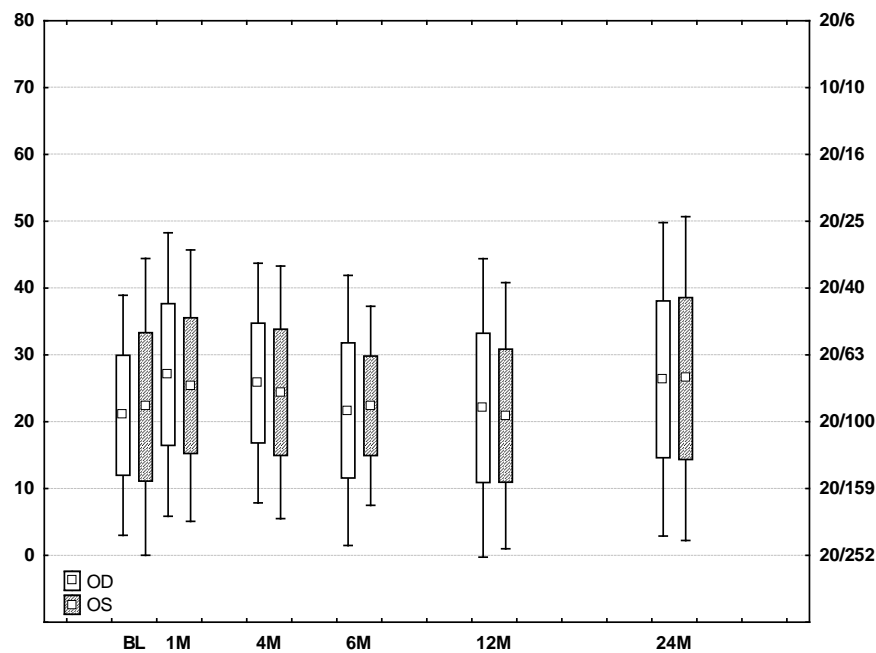
5.4 Distance ETDRS Chart

The Distance ETDRS chart data are displayed in Appendix D and Figure 7 below. The uncorrected distance VA data for controls are shown in Table D-1, and a notable variance in uncorrected VA performance typical of myopes can be observed. However, the data in Table D-2, which provides the corrected VA for the control group, show little to no fluctuation and the variability is greatly reduced. This can be more readily observed in Figure 7A and B. The average differences in corrected vision in controls, as compared with the uncorrected VA, calculate to an improvement of almost seven lines of letters when best corrected.

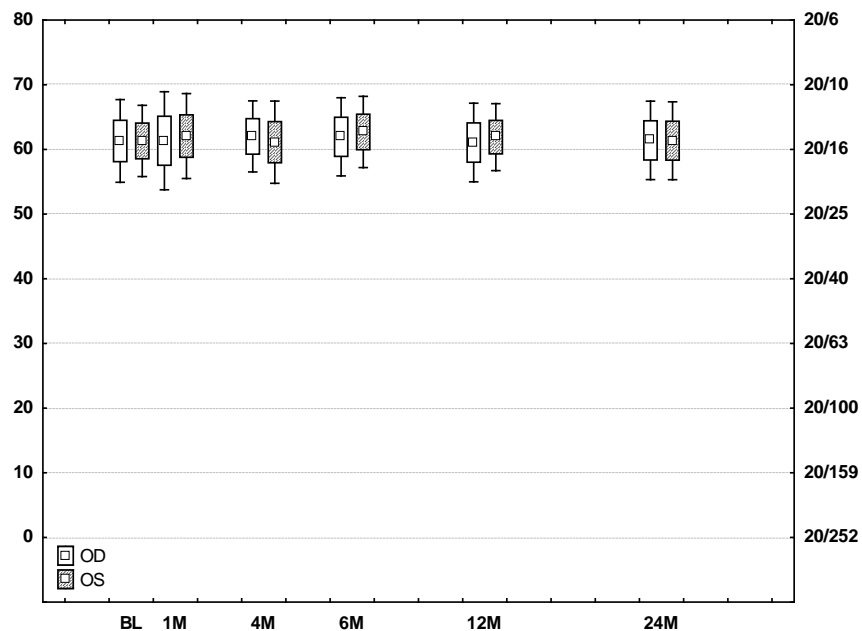
Figure 8A and B, and Tables D-3 and D-4, display the corresponding uncorrected and corrected distance vision data for the surgically treated subjects. The uncorrected data show, as expected, great improvement after PRK surgery compared to presurgical uncorrected baselines and a slight trend, not statistically significant, towards improvement in VA over time. Likewise, the corrected data show very good stability over time with a slight trend towards better VA that is also not statistically significant. However, comparison of the uncorrected VA data in Figure 8A (Table D-3) with the corrected data in Figure 8B (Table D-4) reveals larger differences for OD, OS, and OU at each time evaluation. Also, comparison of the uncorrected post-PRK data with the corrected data for controls in Figure 7B (Table D-2) shows that the control group performed better at each time period. The clear conclusion is that correcting residual refractive errors after PRK improved ETDRS distance VA performance in this study.

In Figure 9, post-PRK performance with the Distance ETDRS chart was evaluated in terms of losing or gaining one or more lines of letters as compared to best-corrected pre-PRK baselines. Figure 9A shows that much larger percentages of subjects lost a line or more of letters, than gained a line of letters or more, when tested uncorrected after PRK. Even at 2 years post-PRK, 33% lost at least a line, while about 11% gained a line. However, post-PRK performance greatly improved when testing was done with best correction (Fig. 9B). At 24 months post-PRK, about 23% gained at least a line, while only 4% lost a line. Obviously, residual refractive errors were a factor and correcting them resulted in noticeable improvement, at least on this test of high contrast distance VA.

In addition, Distance ETDRS chart testing was conducted on all subjects after cycloplegia with widely dilated pupils. The results shown in Appendix D, Tables D-5 and D-6, reflect little change over time and good repeatability in both controls and PRK-treated subjects for this high-contrast VA test. In fact, a very small improvement can be seen in the PRK-treated group over time. Although the improvement is not statistically significant, it is most probably a result of the postcycloplegic testing being conducted with best correction in place and the positive effect of increased image magnification after PRK. Testing with correction obviously negated any effects from uncorrected residual refractive errors, which when dilated may have been substantial even for small amounts of ametropia. The fact that performance remained relatively constant after PRK meant that there were no significant negative effects, with this high-contrast eyechart, from potential complications with transition zone optics or decentered ablations.

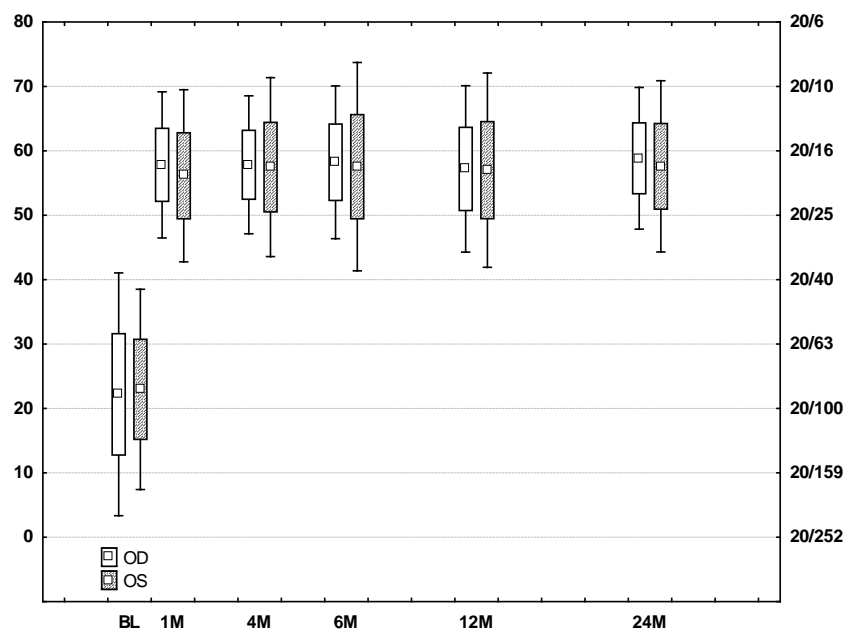


A.

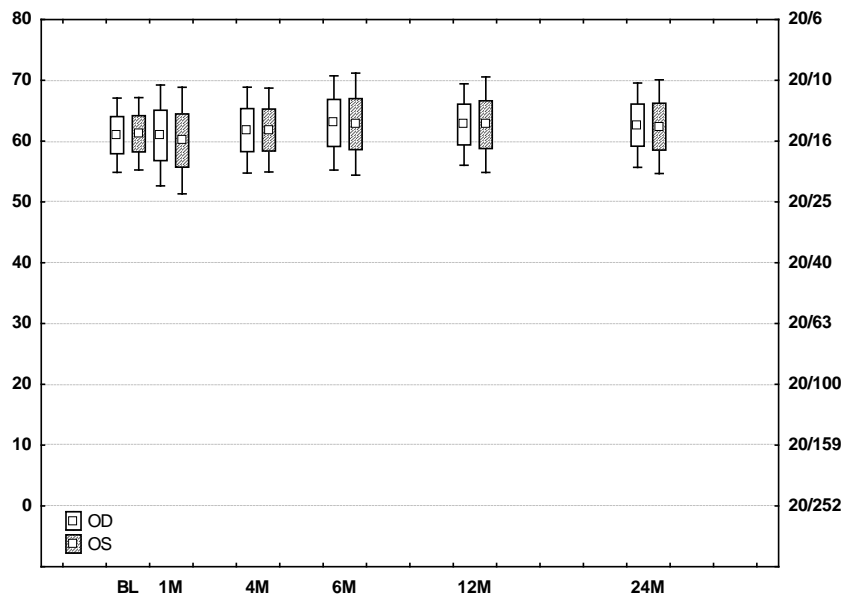


B.

Figure 7. Means and SDs in Control Subjects Plotted at Initial Baseline (BL) and the 1-, 4-, 6-, 12-, and 24-Mo Follow-Up Evaluations for Distance ETDRS Chart Testing with (A) No Correction and (B) Best Correction (Left Vertical Scale Represents Number of Letters Correctly Identified; Right Vertical Scale Represents Snellen Equivalent Visual Acuity)

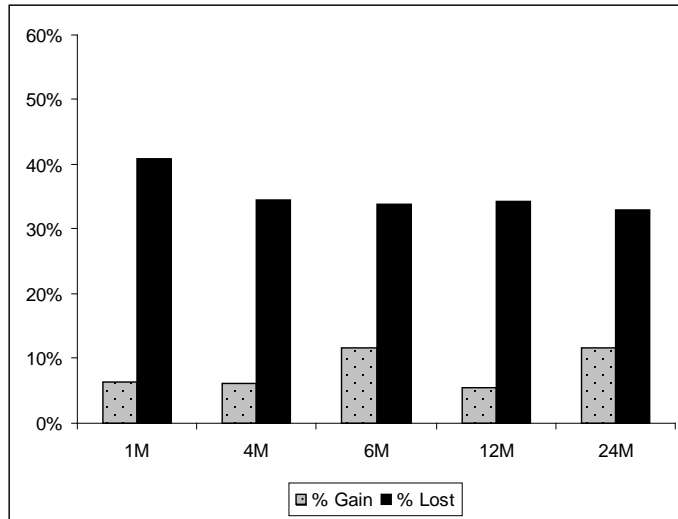


A.

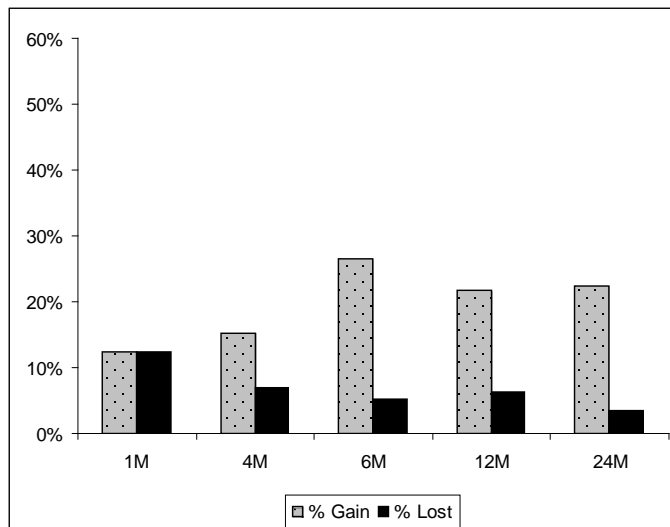


B.

Figure 8. Means and SDs in Treated Subjects Plotted at Initial Baseline (BL) and the 1-, 4-, 6-, 12-, and 24-Months Post-PRK Evaluations for Distance ETDRS Chart Testing with (A) No Correction and (B) Best Correction (Left Vertical Scale Represents Number of Letters Correctly Identified; Right Vertical Scale Represents Snellen Equivalent Visual Acuity)



A.



B.

Figure 9. Percentages of Treated Subjects at the 1-, 4-, 6-, 12-, and 24-Mo Post-PRK Evaluations That Gained or Lost at Least One Line of Letters, Compared to Their Best-Corrected Presurgical Baseline, on the Distance ETDRS Chart with (A) No correction and (B) Best Correction

5.5 Bailey-Lovie Low-Contrast Chart

Data from testing with the Bailey-Lovie eyechart for low-contrast visual acuity are provided in Appendix E and Figures 10 and 11. It should be noted that no uncorrected data were taken for controls or for treated subjects at pre-PRK baseline. Only best-corrected B-L low-contrast VA data were collected for controls and they are shown in Figure 10 and Table E-1. As anticipated, very little variance or variability existed in the data for the control subjects because they were always tested with maximal correction at each time evaluation. Figure 11 and

Tables E-2 and E-3 display the corresponding data for the PRK surgically treated subjects both uncorrected and corrected. The data in Figure 11A show that after PRK surgery uncorrected low-contrast VA does not return to presurgical best-corrected levels at baseline, and the difference is a clinically significant one line of letters at most times. Figure 11B and Table E-3 show that post-PRK corrected performance is very stable over time with a slight trend towards VA better than baseline that is not statistically significant. Clinically significant differences of at least one line of letters were also found for OD, OS, and OU at each time evaluation by comparing the uncorrected VA data in Figure 11A (Table E-2) with the corrected data in Figure 11B (Table E-3). In addition, comparison of the uncorrected post-PRK data with the corrected data for controls in Figure 10 (Table E-1) shows that the control group performed better at each time period. The control group data were remarkably similar to the post-PRK corrected data; both were noticeably better than the uncorrected post-PRK data. Therefore, correcting residual refractive errors after PRK improved VA performance on the B-L low-contrast chart in this study.

Performance on the Bailey-Lovie low-contrast chart was also evaluated in terms of losing or gaining one or more lines of letters post-PRK as compared to best-corrected pre-PRK baselines. Figure 12A shows that much larger percentages of subjects lost a line or more of letters, than gained a line of letters or more, when tested uncorrected after PRK. However, post-PRK performance greatly improved when testing was done with best correction (Fig. 12B). It is unequivocal that residual refractive errors were a factor and correcting them resulted in noticeable improvement in this low-contrast VA test.

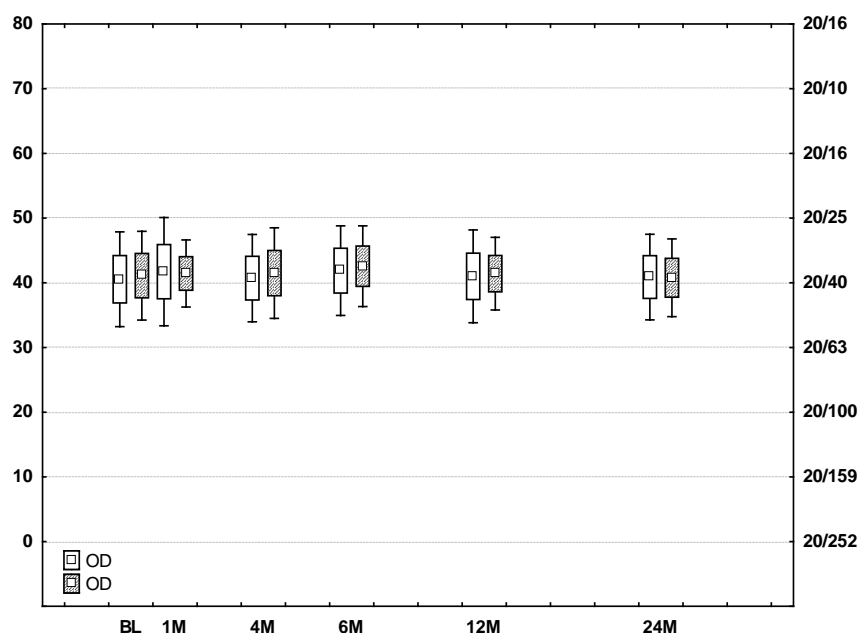
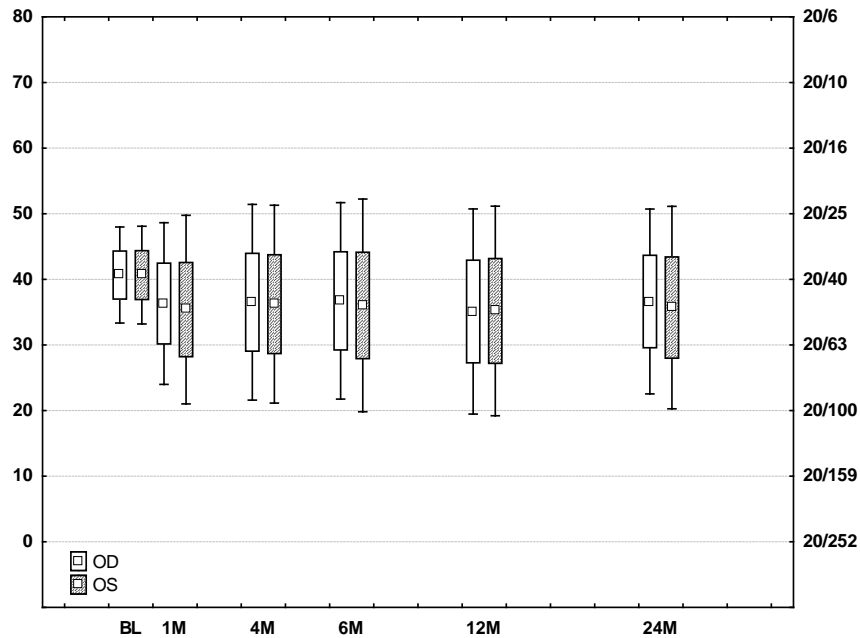
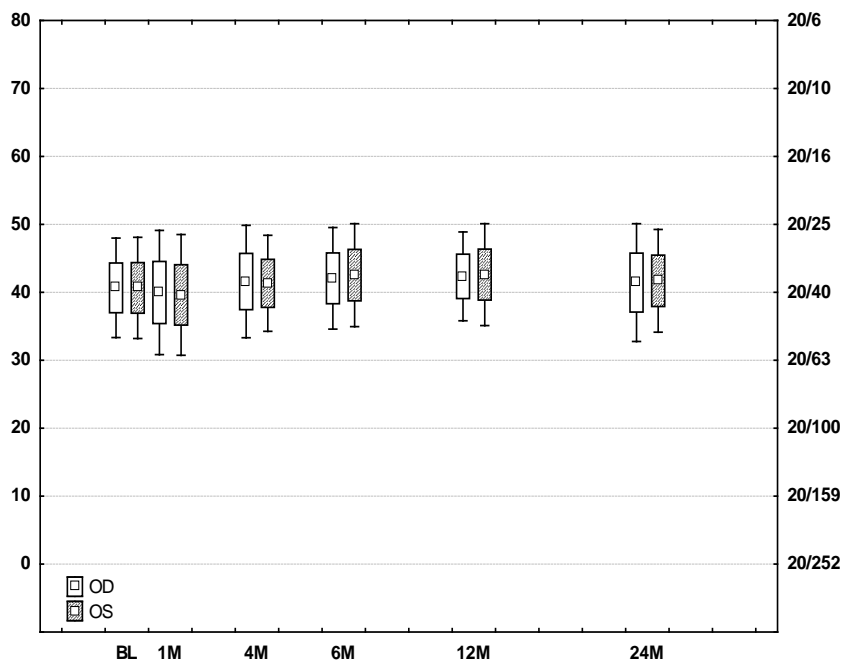


Figure 10. Means and SDs in Control Subjects Plotted at Initial Baseline (BL) and the 1-, 4-, 6-, 12-, and 24-Mo Follow-Up Evaluations for Bailey-Lovie Low-Contrast Eyechart Testing with Best Correction (Left Vertical Scale Represents Number of Letters Correctly Identified; Right Vertical Scale Represents Snellen Equivalent Visual Acuity)

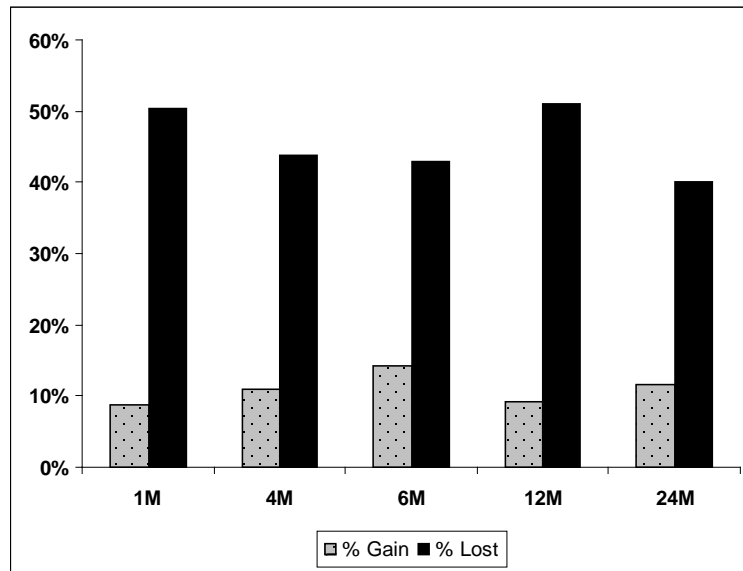


A.

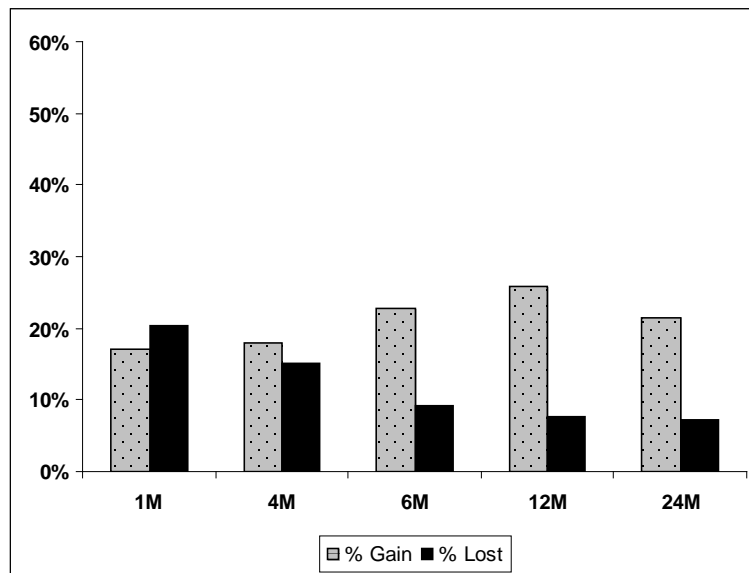


B.

Figure 11. Means and SDs in Treated Subjects Plotted at Initial Baseline (BL) (All with Best Correction) and the 1-, 4-, 6-, 12-, and 24-Mo Post-PRK Evaluations for the Bailey-Lovie Low-Contrast Chart Testing with (A) No Correction and (B) Best Correction (Left Vertical Scale Represents Number of Letters Correctly Identified; Right Vertical Scale Represents Snellen Equivalent Visual Acuity)



A.



B.

Figure 12. Percentages of Treated Subjects at the 1-, 4-, 6-, 12-, and 24-Mo Post-PRK Evaluations That Gained or Lost at Least One Line of Letters, Compared to Their Best-Corrected Presurgical Baseline, on the Bailey-Lovie Low-Contrast Chart with (A) No Correction and (B) Best Correction

Finally, Bailey-Lovie low-contrast chart testing was conducted on all subjects after cycloplegia and mydriasis was achieved. The results, shown in Tables E-4 and E-5 in Appendix E, show little change over time and relatively good repeatability in both controls and PRK-treated subjects considering that this is a low-contrast VA test. A very small decrease of more than one letter can be noted in the PRK-treated group at 1 and 4 months that returns to baseline levels at 6 months and beyond. Although this is not statistically significant, it may reflect some of the changes that occur early in the post-PRK healing process. Once again, it should be noted that all postcycloplegic testing was conducted with best correction in place. This obviously negated the effects from uncorrected residual refractive errors, which would have been substantial even for small amounts of ametropia.

5.6 Rabin Small Letter Contrast Test

The Rabin SLCT data are provided in Tables F-1 to F-3 in Appendix F. Statistical analysis was performed using units of log CS, but the Rabin SLCT data are displayed in more understandable values as number of letters read correctly. As appropriate, only data taken with best correction were collected for controls and are shown in Table F-1. A significant trend in the control data towards reduced performance over time can be noted even though the control subjects were always tested with maximal correction at each time evaluation. This perplexing trend is notable at the 12-month evaluation and more so at 24 months where the degradation equates to a nearly two-lines-of-letters decrease. It appears that something inherently changed at the 12-month evaluation and this downward trend continued at 24 months. Potential explanations affecting the data might include inadvertent alterations over time in the testing distance, lighting level, patient instructions, or possibly changes in the chart itself, e.g., fading, yellowing, decreasing contrast, etc.

Tables F-2 and F-3 display the corresponding uncorrected and corrected data for the PRK surgically treated subjects. The uncorrected data for treated subjects after PRK surgery show good stability initially that again drops off at 12 and 24 months. The corrected data show a drop in letters at 1 month that gradually improves out to 6 months and declines slightly at 24 months. Because of the degradation over time in chart performance, unrelated to PRK, only comparisons of the uncorrected VA data in Table F-2 with the corrected data in Table F-3 were explored. These comparisons revealed that post-PRK corrected performance was better at clinically significant levels for OD, OS, and OU at each evaluation time. Also, comparison of the uncorrected post-PRK data in Table F-2 with the corrected data for controls in Table F-1 shows that the control group performed better at each time period. The post-PRK corrected data were similar to the control data, perhaps even a little better, and both the control and post-PRK corrected data were noticeably better than the uncorrected post-PRK data. Accordingly, it can be concluded that correcting residual refractive errors after PRK also improved contrast sensitivity performance for small letters in this study. However, the consistent drop-off in performance in controls and treated subjects alike at 12 and 24 months further confirmed that something changed over time with this particular contrast sensitivity chart or the laboratory conditions employed. Because the etiology remained unknown, the Rabin SLCT chart could not be recommended for further use in clinical or research studies and was dropped from the testing battery. This prompted evaluation of a newer chart system, the Precision Vision High- and Low-Contrast Charts, for efficacy in research studies and their potential deployability to USAF clinics

worldwide. However, development of these test charts occurred outside the study protocol because they were not available when the study began.

5.7 Armed Forces Optec 2300 Vision Tester

The Armed Forces Optec 2300 Vision Tester was also used to test subjects, but only at the 24-month evaluation. The data are displayed in Appendix G. Table G-1 shows the control data and Table G-2 displays the data for treated subjects, both corrected and uncorrected. Even though OVT testing was not conducted at presurgical baselines or any follow-up evaluations during the first year, the 24-month data do help confirm that uncorrected post-PRK VA performance was inferior to performance with best correction, or corrected performance in controls. As discussed earlier, in accordance with AFI 48-123, the OVT is the required test device for aeromedical vision testing at USAF bases in the field for aviation physical exams and waiver evaluations. In this capacity as a pass/fail vision screening device, it performs very adequately for the USAF but has limited use as a research tool.

6.0 RECOMMENDATIONS

While the PRK procedure was generally regarded to be highly successful with respect to reducing dependence on optical appliances in the civilian population, its suitability for military operations was largely unknown (Ref 46). Before implementing this relatively new surgical procedure for USAF aviators, the Air Force Chief of Staff directed that Armstrong Laboratory develop tests that detect the complications of PRK and work with the Air Force Medical Operations Agency to develop new aeromedical standards applicable for PRK if required. Accordingly, the Aerospace Ophthalmology Branch at Brooks AFB, TX, designed a comprehensive scientific study to evaluate the then novel surgical procedure of PRK. The results were to be used to determine the appropriateness of PRK for USAF aviators and, if it was proven safe and effective, to form the basis for developing new aeromedical standards appropriate for this procedure. Aeromedical standards for operational flying are inherently different than standard clinical criteria in the civilian community or Federal Aviation Administration requirements (Ref 47). Problems that are termed minor or inconsequential by the civilian community may become potentially life threatening in military environments (Ref 48). USAF pilots and aviators are an extremely valuable resource, and their health and safety must be vigilantly protected (Ref 49). Accordingly, the job of the Aerospace Ophthalmology Branch at the USAFSAM is to be the sentinel for aviators and ensure that USAF aircrew visual performance remains optimized across all potential operational scenarios. As part of the larger USAF comprehensive PRK study (Ref 36,37,39), this investigation was specifically designed to identify any negative effects on refractive error and high- and low-contrast visual acuity performance.

The results of this study revealed that low to moderate post-PRK residual refractive errors were present in many subjects. A relatively large percentage of eyes (OD: 13.9%; OS: 17.9%) had a clinically significant value of -0.50 D or more of spherical equivalent myopia initially after surgery, and the percentages increased over 24 months. Overcorrection, or residual hyperopia, was less common, especially after the first month post-PRK. Residual astigmatism was a factor in approximately 10% of eyes at 24 months even though presurgical astigmatism was limited to 1 D or less. Testing with the battery of eyecharts revealed the following:

- There was a significant improvement in uncorrected mean near VA after PRK surgery (Table C-3).
- Mean uncorrected-distance high-contrast vision was greatly improved after PRK, but it did not quite return to presurgical best-corrected levels (Figure 8A and B).
- Without correction after PRK, more subjects lost at least one line of letters of distance high-contrast VA versus gained a line (Figure 9A), but more subjects gained a line when best corrected after surgery (Figure 9B).
- Mean uncorrected low-contrast VA was greatly improved after PRK, but it did not return to presurgical best-corrected levels (Figure 11A).
- Without correction, more subjects lost at least one line of letters of distance low-contrast VA after PRK than gained a line (Figure 12A), but more subjects gained a line when best corrected after surgery (Figure 12B).
- Testing under cycloplegia with high-contrast and low-contrast charts revealed no differences in post-PRK best-corrected performance (Tables D-6 and E-5).
- A small letter test of contrast sensitivity showed that post-PRK performance without correction was not as good as with best correction (Tables F-1 to F-3).
- Testing with the Armed Forces OVT confirmed that, at 24 months post-PRK, uncorrected performance was inferior to performance with best correction, or with corrected performance in controls (Tables G-1 and G-2).

Because PRK for aviators is an elective procedure to surgically correct myopia, loss of best-corrected spectacle vision was a major concern. Loss of best-corrected VA after PRK did not happen to any subjects in this study. A critical point gleaned from the post-PRK data was that VA, especially low-contrast vision, was typically decreased during the first 1-4 months even when subjects were tested with best correction. Obviously, this performance decrement was not due to uncorrected refractive error but more likely to the subtle subclinical healing response and stromal collagen remodeling that take place after the surgery (Ref 50). Other potential causes for the decreased vision include corneal haze, irregular astigmatism, decentered ablations, higher order aberrations, tear film instability, etc. (Ref 51). Therefore, current recommendations for post-PRK aviators must emphasize retraining and a gradual return to full flying duties and solo flight.

The major area of postoperative concern found in this study was the potential for residual refractive errors (Ref 52). Post-PRK refractive complications may include undercorrection, overcorrection, induced astigmatism, and anisometropia. The primary concern for distance visual acuity was undercorrection and/or regression over time similar to the myopic trend reported in Table 2 between UPT and later in mid-career. Low to moderate residual refractive error after refractive surgery may be operationally significant in aviators, especially if not optimally corrected. The prevalence in this study for PRK-treated eyes to have low to moderate residual refractive errors, defined as equal to or more than -0.50 D of myopia (spherical equivalent) on cycloplegic refraction, was relatively high. Yet very few of these subjects wore corrective lenses. Larger amounts of preoperative myopia outside the criteria of this study would be expected to have less likelihood of achieving emmetropia post-PRK. When tested with best optical correction, however, performance on the various charts often improved to as good as, or better than, pre-PRK baseline values. The fundamental question is whether most individuals, particularly aviators, will wear relatively minor optical corrections in spectacles after refractive

surgery, especially if they meet the current 20/20 requirement uncorrected. Failure to do so, however, may mean that certain visual performance parameters would be compromised and result in operational limitations of significance. For example, pilots who are only 20/20 uncorrected after PRK would need twice the distance to acquire and/or identify certain targets as compared to their performance when best corrected to a possible 20/10 with spectacles or contact lenses. Potentially large differences may exist in target acquisition distances for detecting a bogey (10 miles versus 5 miles) and in critical reaction times.

With further confirmation of the refractive data, the Aerospace Ophthalmology Branch may recommend that aviators, especially younger ones, be overcorrected during PRK surgery by 0.25 to 0.50 D more than their myopic correction. This would negate the postsurgical myopic trend and allow more aviators to be able to fly without spectacles or contact lenses postoperatively, and fewer retreatments would be necessary. Previous PRK studies had shown up to 20% of individuals may need retreatment for residual myopia after PRK. The indications for retreatments are usually undercorrection and/or regression. Retreatment is best if done after 6 months of the original treatment, once the refraction is stable, and would create significant operational and mission support problems if needed on a widespread basis. On the other hand, new treatment technologies may counter much of the residual refractive error problem found in this study. However, the negative effects on visual acuity and contrast sensitivity from most residual refractive errors would undoubtedly trump the effects of almost any other postsurgical complication.

It can be accurately stated that PRK is an effective method to reduce dependence on spectacles or contact lenses in most individuals. Its applicability for USAF aviators must include the understanding that, although most subjects will be 20/20 without spectacle correction, due to myopic regression a number of subjects may again have to wear glasses at some point in their flying career to meet the 20/20 minimum aeromedical standard. Furthermore, some post-PRK aviators might have to wear optical correction to regain their baseline VA or an acceptable level of visual performance for low-contrast vision. Less than perfect eyesight may be a problem during critical flight scenarios, e.g., in the landing pattern; while refueling; air-to-air and air-to-ground target acquisition; or in visually deprived conditions such as low light, haze, fog, rain, or at night, etc. For those post-PRK patients who need correction, but choose not to wear spectacles, contact lenses are a possibility. However, special post-PRK contact lenses are not routinely available and require specialized expertise to fit. Also, these unique rigid gas permeable contact lenses might be difficult to provide in remote locations. Regardless, more work needs to be done over the long term to evaluate visual function in post-PRK patients with minor uncorrected residual refractive errors, especially those who may be able to "pass" a high-contrast Snellen visual acuity test of only 20/20, i.e., barely pass aeromedical vision standards allowing them to fly without optical correction. If post-PRK testing is limited to only high-contrast Snellen visual acuity, problems may be missed in a subset of individuals who are evident only in certain operational situations, e.g., flying in bad weather or low-contrast atmospheric conditions, settings where the prevailing ambient light is limited to mesopic levels.

Finally, it can be stated unequivocally that residual refractive errors, degraded uncorrected VA and CS, increased optical aberrations, and light scatter are present in some patients after refractive surgery. Therefore, it is essential that visual performance in post-PRK patients be comprehensively tested not only under standard photopic high-contrast conditions but under other conditions including low light, reduced contrast, mesopic glare, and with NVGs. The USAF Aviation PRK Study was designed to comprehensively evaluate a wide range of

parameters to detect potential QoV and subtle post-PRK complications. Visual acuity and residual refractive errors have to be precisely measured and evaluated more intensely than during routine clinical examinations to ensure that the aviator patient fully appreciates the risks, complications, and visual expectations with PRK to make a fully informed decision about an elective surgery. This study, as a vital part of the comprehensive study, precisely measured photopic visual performance on multiple VA tests, including two low-contrast charts, and carefully evaluated residual refractive error, i.e., the amount of refractive error remaining after PRK. Although it had some basic design constraints and resource limitations, this initial effort provides the foundation for an expanded program to comprehensively evaluate all post-CRS aeromedical and QoV issues.

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APPENDIX A

Refractive Errors (Spherical)

Mean values and SDs from manifest and cycloplegic refractions at initial baseline and each follow-up evaluation. Values are spherical equivalents in diopters.

Table A-1. Control Subjects

| Eye | Baseline (N=20) Mean (SD) | 1 Mo (N=18) Mean (SD) | 4 Mo (N=18) Mean (SD) | 6 Mo (N=16) Mean (SD) | 12 Mo (N=18) Mean (SD) | 24 Mo (N=18) Mean (SD) |
|-------------------------------|------------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
| Manifest Refraction | | | | | | |
| OD | -3.38 (±1.27) | -3.50 (±1.39) | -3.51 (±1.21) | -3.52 (±1.23) | -3.35 (±1.23) | -3.31 (±1.18) |
| OS | -3.41 (±1.18) | -3.52 (±1.28) | -3.55 (±1.09) | -3.45 (±1.15) | -3.41 (±1.19) | -3.31 (±1.12) |
| Cycloplegic Refraction | | | | | | |
| OD | -3.18 (±1.28) | -3.30 (±1.37) | -3.35 (±1.22) | -3.29 (±1.22) | -3.10 (±1.10) | -3.09 (±1.20) |
| OS | -3.16 (±1.10) | -3.30 (±1.33) | -3.38 (±1.16) | -3.26 (±1.19) | -3.05 (±1.13) | -3.07 (±1.14) |

Table A-2. PRK-Treated Subjects

| Eye | Baseline (N=79) Mean (SD) | 1 Mo (N=78) Mean (SD) | 4 Mo (N=72) Mean (SD) | 6 Mo (N=76) Mean (SD) | 12 Mo (N=72) Mean (SD) | 24 Mo (N=56) Mean (SD) |
|-------------------------------|------------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
| Manifest Refraction | | | | | | |
| OD | -3.60 (±1.52) | -0.05 (±0.55) | -0.32 (±0.47) | -0.38 (±0.45) | -0.52 (±0.40) | -0.38 (±0.36) |
| OS | -3.52 (±1.49) | -0.24 (±0.63) | -0.31 (±0.55) | -0.43 (±0.51) | -0.46 (±0.49) | -0.39 (±0.48) |
| Cycloplegic Refraction | | | | | | |
| OD | -3.28 (±1.49) | +0.28 (±0.57) | -0.03 (±0.44) | -0.05 (±0.47) | -0.20 (±0.48) | -0.09 (±0.44) |
| OS | -3.23 (±1.47) | +0.13 (±0.60) | -0.05 (±0.57) | -0.09 (±0.56) | -0.13 (±0.52) | -0.07 (±0.48) |

APPENDIX B

Refractive Errors (Astigmatism)

Mean and SD values for astigmatic correction from cycloplegic refractions at initial baseline and each follow-up evaluation. All values in diopters of cylinder power.

Table B-1. Control Subjects

| Eye | Baseline (N=20) Mean (SD) | 1 Mo (N=18) Mean (SD) | 4 Mo (N=18) Mean (SD) | 6 Mo (N=16) Mean (SD) | 12 Mo (N=18) Mean (SD) | 24 Mo (N=18) Mean (SD) |
|-----|------------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
| OD | 0.60 (±0.35) | 0.60 (±0.31) | 0.61 (±0.38) | 0.67 (±0.28) | 0.53 (±0.34) | 0.57 (±0.38) |
| OS | 0.48 (±0.31) | 0.42 (±0.26) | 0.46 (±0.33) | 0.53 (±0.29) | 0.35 (±0.27) | 0.42 (±0.28) |

Table B-2. PRK-Treated Subjects

| Eye | Baseline (N=79) Mean (SD) | 1 Mo (N=78) Mean (SD) | 4 Mo (N=72) Mean (SD) | 6 Mo (N=74) Mean (SD) | 12 Mo (N=70) Mean (SD) | 24 Mo (N=53) Mean (SD) |
|-----|------------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
| OD | 0.47 (±0.34) | 0.37 (±0.33) | 0.36 (±0.32) | 0.37 (±0.30) | 0.29 (±0.30) | 0.28 (±0.29) |
| OS | 0.47 (±0.37) | 0.35 (±0.27) | 0.27 (±0.24) | 0.31 (±0.27) | 0.30 (±0.26) | 0.26 (±0.28) |

APPENDIX C

Near ETDRS Chart

Means and SDs for number of letters read correctly

Table C-1. Controls (Uncorrected)

| Eye | Baseline (N=20) Mean (SD) | 1 Mo (N=17) Mean (SD) | 4 Mo (N=18) Mean (SD) | 6 Mo (N=15) Mean (SD) | 12 Mo (N=18) Mean (SD) | 24 Mo (N=18) Mean (SD) |
|-----|------------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
| OD | 55.0 (16.7) | 55.2 (14.3) | 55.7 (16.4) | 57.8 (15.2) | 57.8 (14.1) | 60.0 (15.3) |
| OS | 56.8 (14.6) | 55.5 (15.2) | 55.3 (15.6) | 58.9 (12.7) | 57.6 (15.2) | 60.4 (14.7) |
| OU | 61.9 (11.8) | 62.8 (12.9) | 61.4 (13.4) | 63.7 (11.2) | 63.7 (11.3) | 65.3 (11.2) |

Table C-2. Controls (Corrected)

| Eye | Baseline (N=19) Mean (SD) | 1 Mo (N=18) Mean (SD) | 4 Mo (N=18) Mean (SD) | 6 Mo (N=16) Mean (SD) | 12 Mo (N=17) Mean (SD) | 24 Mo (N=18) Mean (SD) |
|-----|------------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
| OD | 71.6 (7.1) | 70.0 (8.4) | 71.1 (7.2) | 71.9 (7.1) | 68.6 (10.1) | 66.2 (13.7) |
| OS | 72.0 (6.1) | 70.9 (8.5) | 71.7 (8.2) | 72.5 (6.3) | 70.6 (9.1) | 68.0 (11.1) |
| OU | 72.6 (6.2) | 72.1 (7.0) | 72.8 (6.6) | 73.4 (5.3) | 71.4 (8.6) | 70.7 (9.2) |

Table C-3. PRK Treated (Uncorrected)

| Eye | Baseline (N=79) Mean (SD) | 1 Mo (N=78) Mean (SD) | 4 Mo (N=72) Mean (SD) | 6 Mo (N=76) Mean (SD) | 12 Mo (N=72) Mean (SD) | 24 Mo (N=56) Mean (SD) |
|-----|------------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
| OD | 54.4 (19.9) | 71.1 (5.8) | 72.2 (4.4) | 72.2 (5.2) | 73.1 (3.4) | 71.5 (5.4) |
| OS | 55.2 (18.2) | 70.4 (5.6) | 72.8 (4.4) | 72.4 (4.5) | 72.8 (3.6) | 71.8 (5.9) |
| OU | 60.1 (16.1) | 73.4 (3.7) | 73.7 (3.6) | 73.9 (3.3) | 74.4 (1.6) | 73.4 (4.4) |

Table C-4. PRK Treated (Corrected)

| Eye | Baseline (N=79) Mean (SD) | 1 Mo (N=78) Mean (SD) | 4 Mo (N=71) Mean (SD) | 6 Mo (N=76) Mean (SD) | 12 Mo (N=72) Mean (SD) | 24 Mo (N=56) Mean (SD) |
|------------|--|--|--|--|---|---|
| OD | 72.0 (5.4) | 72.7 (3.8) | 72.6 (5.5) | 72.6 (4.9) | 73.3 (4.5) | 74.9 (6.2) |
| OS | 72.3 (5.0) | 71.8 (5.6) | 72.8 (4.9) | 73.1 (4.3) | 72.9 (4.4) | 72.2 (6.4) |
| OU | 73.5 (3.9) | 73.7 (3.1) | 73.5 (4.4) | 73.7 (3.6) | 74.2 (2.8) | 73.3 (4.6) |

APPENDIX D

Distance ETDRS Chart

Means and SDs for number of letters read correctly

Table D-1. Controls (Uncorrected)

| Eye | Baseline (N=19) Mean (SD) | 1 Mo (N=18) Mean (SD) | 4 Mo (N=18) Mean (SD) | 6 Mo (N=16) Mean (SD) | 12 Mo (N=17) Mean (SD) | 24 Mo (N=18) Mean (SD) |
|-----|------------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
| OD | 20.9 (9.0) | 27.0 (10.6) | 25.7 (9.0) | 21.6 (10.1) | 22.0 (11.2) | 26.3 (11.7) |
| OS | 22.2 (11.1) | 25.3 (10.2) | 24.3 (8.2) | 22.3 (6.3) | 20.8 (9.1) | 26.4 (11.1) |
| OU | 29.1 (10.5) | 33.7 (9.8) | 32.1 (9.0) | 30.9 (8.8) | 30.4 (12.2) | 34.8 (13.2) |

Table D-2. Controls (Corrected)

| Eye | Baseline (N=19) Mean (SD) | 1 Mo (N=18) Mean (SD) | 4 Mo (N=18) Mean (SD) | 6 Mo (N=16) Mean (SD) | 12 Mo (N=17) Mean (SD) | 24 Mo (N=18) Mean (SD) |
|-----|------------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
| OD | 61.3 (3.2) | 61.3 (3.8) | 62.0 (2.7) | 61.9 (3.0) | 61.1 (3.0) | 61.4 (3.0) |
| OS | 61.3 (2.8) | 62.1 (3.3) | 61.1 (3.2) | 62.7 (2.8) | 61.9 (2.6) | 61.3 (3.0) |
| OU | 64.0 (2.2) | 63.9 (3.0) | 63.0 (2.8) | 64.8 (3.1) | 63.5 (2.9) | 64.1 (2.7) |

Table D-3. PRK Treated (Uncorrected)

| Eye | Baseline (N=79) Mean (SD) | 1 Mo (N=78) Mean (SD) | 4 Mo (N=72) Mean (SD) | 6 Mo (N=76) Mean (SD) | 12 Mo (N=72) Mean (SD) | 24 Mo (N=56) Mean (SD) |
|-----|------------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
| OD | 22.2 (9.4) | 57.8 (5.7) | 57.8 (5.4) | 58.2 (5.9) | 57.2 (6.5) | 58.8 (5.5) |
| OS | 23.0 (7.8) | 56.1 (6.7) | 57.5 (6.9) | 57.5 (8.1) | 57.0 (7.5) | 57.6 (6.6) |
| OU | 30.9 (9.1) | 61.5 (4.7) | 62.1 (3.7) | 62.2 (5.3) | 61.7 (5.7) | 62.4 (3.8) |

Table D-4. PRK Treated (Corrected)

| Eye | Baseline (N=79) Mean (SD) | 1 Mo (N=78) Mean (SD) | 4 Mo (N=72) Mean (SD) | 6 Mo (N=76) Mean (SD) | 12 Mo (N=72) Mean (SD) | 24 Mo (N=56) Mean (SD) |
|------------|--|--|--|--|---|---|
| OD | 61.0 (3.0) | 60.9 (4.1) | 61.8 (3.5) | 63.0 (3.9) | 62.7 (3.3) | 62.6 (3.5) |
| OS | 61.2 (3.0) | 60.1 (4.4) | 61.8 (3.4) | 62.8 (4.2) | 62.7 (3.9) | 62.4 (3.8) |
| OU | 63.4 (2.7) | 63.7 (3.6) | 64.2 (2.8) | 65.7 (3.3) | 65.3 (2.9) | 64.9 (3.4) |

Table D-5. Controls (Postcycloplegia Best Corrected)

| Eye | Baseline (N=20) Mean (SD) | 1 Mo (N=18) Mean (SD) | 4 Mo (N=18) Mean (SD) | 6 Mo (N=16) Mean (SD) | 12 Mo (N=17) Mean (SD) | 24 Mo (N=18) Mean (SD) |
|------------|--|--|--|--|---|---|
| OD | 59.0 (±3.1) | 58.1 (±3.0) | 59.0 (±3.0) | 59.3 (±3.5) | 58.1 (±3.6) | 58.7 (±2.7) |
| OS | 59.9 (±3.2) | 59.3 (±3.1) | 58.7 (±2.2) | 59.8 (±3.0) | 59.2 (±2.8) | 59.2 (±2.3) |

Table D-6. PRK Treated (Postcycloplegia Best Corrected)

| Eye | Baseline (N=79) Mean (SD) | 1 Mo (N=78) Mean (SD) | 4 Mo (N=73) Mean (SD) | 6 Mo (N=75) Mean (SD) | 12 Mo (N=72) Mean (SD) | 24 Mo (N=54) Mean (SD) |
|------------|--|--|--|--|---|---|
| OD | 59.4 (±3.5) | 59.4 (±3.9) | 59.7 (±3.8) | 60.7 (±3.8) | 60.1 (±4.0) | 60.2 (±3.6) |
| OS | 59.1 (±2.9) | 58.7 (±4.3) | 59.8 (±3.6) | 60.2 (±4.0) | 60.2 (±3.8) | 60.0 (±3.7) |

APPENDIX E

Bailey-Lovie 10% Contrast Chart

Means and SDs for number of letters read correctly

Table E-1. Controls (Corrected)

| Eye | Baseline (N=20) Mean (SD) | 1 Mo (N=18) Mean (SD) | 4 Mo (N=18) Mean (SD) | 6 Mo (N=16) Mean (SD) | 12 Mo (N=17) Mean (SD) | 24 Mo (N=18) Mean (SD) |
|-----|------------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
| OD | 40.6 (3.7) | 41.7 (4.2) | 40.7 (3.4) | 41.9 (3.5) | 41.0 (3.6) | 40.9 (3.3) |
| OS | 41.1 (3.4) | 41.4 (2.6) | 41.5 (3.5) | 42.6 (3.1) | 41.4 (2.8) | 40.8 (3.0) |
| OU | 44.4 (1.9) | 44.1 (2.2) | 43.9 (1.9) | 45.4 (1.9) | 44.9 (2.6) | 44.2 (2.5) |

Table E-2. PRK Treated (Uncorrected)

| Eye | Baseline (N=79) Mean (SD) | 1 Mo (N=75) Mean (SD) | 4 Mo (N=69) Mean (SD) | 6 Mo (N=78) Mean (SD) | 12 Mo (N=72) Mean (SD) | 24 Mo (N=56) Mean (SD) |
|-----|------------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
| OD | NA | 36.3 (6.2) | 36.5 (7.5) | 36.7 (7.5) | 35.1 (7.8) | 36.6 (7.0) |
| OS | NA | 35.4 (7.2) | 36.2 (7.5) | 36.0 (8.1) | 35.2 (8.0) | 35.7 (7.7) |
| OU | NA | 40.8 (4.8) | 41.2 (4.8) | 41.3 (5.9) | 40.6 (6.9) | 41.5 (5.0) |

Table E-3. PRK Treated (Corrected)

| Eye | Baseline (N=79) Mean (SD) | 1 Mo (N=78) Mean (SD) | 4 Mo (N=72) Mean (SD) | 6 Mo (N=76) Mean (SD) | 12 Mo (N=72) Mean (SD) | 24 Mo (N=56) Mean (SD) |
|-----|------------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
| OD | 40.7 (3.7) | 40.0 (4.6) | 41.6 (4.1) | 42.0 (3.7) | 42.3 (3.3) | 41.4 (4.3) |
| OS | 40.6 (3.7) | 39.6 (4.4) | 41.3 (3.5) | 42.5 (3.8) | 42.6 (3.7) | 41.7 (3.8) |
| OU | 43.6 (2.6) | 43.6 (3.1) | 44.9 (2.7) | 45.0 (2.9) | 45.4 (2.8) | 44.7 (3.0) |

Table E-4. Controls (Postcycloplegia Best Corrected)

| Eye | Baseline (N=20) Mean (SD) | 1 Mo (N=18) Mean (SD) | 4 Mo (N=18) Mean (SD) | 6 Mo (N=16) Mean (SD) | 12 Mo (N=17) Mean (SD) | 24 Mo (N=18) Mean (SD) |
|------------|--|--|--|--|---|---|
| OD | 31.9 (±6.7) | 31.2 (±6.4) | 32.0 (±4.9) | 33.8 (±6.0) | 31.4 (±6.3) | 31.8 (±5.2) |
| OS | 34.2 (±4.0) | 33.8 (±5.0) | 33.1 (±3.7) | 33.9 (±4.0) | 32.9 (±5.6) | 33.2 (±4.3) |

Table E-5. PRK Treated (Postcycloplegia Best Corrected)

| Eye | Baseline (N=79) Mean (SD) | 1 Mo (N=78) Mean (SD) | 4 Mo (N=73) Mean (SD) | 6 Mo (N=75) Mean (SD) | 12 Mo (N=71) Mean (SD) | 24 Mo (N=54) Mean (SD) |
|------------|--|--|--|--|---|---|
| OD | 32.5 (±5.0) | 31.0 (±5.7) | 30.7 (±4.8) | 32.5 (±5.6) | 32.4 (±5.4) | 32.2 (±5.4) |
| OS | 33.2 (±4.4) | 31.9 ±5.0) | 31.7 (±4.5) | 33.0 (±5.4) | 32.7 (±4.8) | 32.6 (±5.0) |

APPENDIX F

Rabin Small Letter Contrast Chart

Means and SDs for number of letters read correctly

Table F-1. Controls (Corrected)

| Eye | Baseline (N=20) Mean (SD) | 1 Mo (N=18) Mean (SD) | 4 Mo (N=18) Mean (SD) | 6 Mo (N=16) Mean (SD) | 12 Mo (N=18) Mean (SD) | 24 Mo (N=18) Mean (SD) |
|-----|------------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
| OD | 113.5 (12.9) | 111.9 (16.2) | 110.9 (14.6) | 112.4 (16.1) | 106.2 (13.3) | 96.1 (13.7) |
| OS | 116.4 (11.3) | 115.3 (12.5) | 113.3 (15.1) | 113.5 (13.6) | 107.8 (13.4) | 101.7 (13.9) |
| OU | 126.6 (8.7) | 128.3 (7.2) | 125.6 (8.6) | 125.7 (8.4) | 123.6 (8.1) | 116.6 (11.4) |

Table F-2. PRK Treated (Uncorrected)

| Eye | Baseline (N=79) Mean (SD) | 1 Mo (N=74) Mean (SD) | 4 Mo (N=69) Mean (SD) | 6 Mo (N=75) Mean (SD) | 12 Mo (N=71) Mean (SD) | 24 Mo (N=56) Mean (SD) |
|-----|------------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
| OD | NA | 89.6 (31.3) | 86.8 (33.0) | 88.8 (32.8) | 82.4 (30.7) | 83.6 (27.1) |
| OS | NA | 83.5 (35.7) | 86.5 (31.9) | 86.9 (35.4) | 82.4 (32.0) | 81.0 (27.5) |
| OU | NA | 109.6 (23.6) | 112.2 (22.4) | 109.3 (28.7) | 107.0 (24.6) | 105.8 (21.0) |

Table F-3. PRK Treated (Corrected)

| Eye | Baseline (N=79) Mean (SD) | 1 Mo (N=78) Mean (SD) | 4 Mo (N=72) Mean (SD) | 6 Mo (N=76) Mean (SD) | 12 Mo (N=72) Mean (SD) | 24 Mo (N=56) Mean (SD) |
|-----|------------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
| OD | 111.2 (15.8) | 103.0 (22.4) | 108.3 (20.8) | 111.0 (16.1) | 110.6 (16.1) | 101.6 (21.0) |
| OS | 113.7 (16.0) | 100.5 (23.8) | 110.5 (18.2) | 112.4 (16.7) | 110.9 (17.2) | 103.3 (20.1) |
| OU | 126.9 (8.2) | 122.2 (15.1) | 124.0 (14.6) | 125.8 (10.8) | 125.6 (10.0) | 118.9 (15.3) |

APPENDIX G

OVT Visual Acuity Testing

Means and SDs for number of letters read correctly

Table G-1. Controls (Corrected) (24 Mo Postbaseline Only; N=18)

| Eye | Mean | SD |
|-----|-------|-----|
| OD | 94.9 | 7.8 |
| OS | 97.6 | 7.1 |
| OU | 104.6 | 3.7 |

Table G-2. PRK Treated (Uncorrected and Corrected) (24 Mo Post-PRK Only)

| Eye | Uncorrected (N=56) | | Corrected (N=54) | |
|-----|-----------------------|------|---------------------|-----|
| | Mean | SD | Mean | SD |
| OD | 89.8 | 12.9 | 97.8 | 7.0 |
| OS | 91.4 | 12.0 | 99.8 | 5.9 |
| OU | 102.4 | 6.7 | 105.7 | 3.6 |

LIST OF ABBREVIATIONS AND ACRONYMS

| | |
|-------------------|--|
| AFB | Air Force Base |
| AFI | Air Force Instruction |
| AFRL | Air Force Research Laboratory |
| AFROTC | Air Force Reserve Officer Training Corps |
| B-L | Bailey-Lovie |
| cd/m ² | candela per square meter |
| CRS | corneal refractive surgery |
| CS | contrast sensitivity |
| D | diopter |
| ETDRS | Early Treatment of Diabetic Retinopathy Study |
| FAA | Federal Aviation Administration |
| FDA | Food and Drug Administration |
| FLIR | forward looking infrared |
| IRB | institutional review board |
| logMAR | log ₁₀ of the minimum angle of resolution |
| MAR | minimum angle of resolution |
| NVGs | night vision goggles |
| OTS | Officer Training School |
| OVT | Armed Forces Optec 2300 Vision Tester |
| PRK | photorefractive keratectomy |
| QoV | quality of vision |
| SD | standard deviation |

| | |
|---------|---|
| SLCT | small letter contrast test |
| UPT | Undergraduate Pilot Training |
| USAFA | U.S. Air Force Academy |
| USAFSAM | U.S. Air Force School of Aerospace Medicine |
| WHMC | Wilford Hall Medical Center |